UNITED STATES DISTRICT COURT 1 FOR THE DISTRICT OF NEW JERSEY 2 CIVIL ACTION NUMBER: 3 19-md-02875-RBK-JS 4 IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION STATUS CONFERENCE and 5 DISCOVERY CONFERENCE WITH ORAL OPINION ON REDACTION 6 ISSUE AND RULINGS ON PLAINTIFFS' DISCOVERY 7 DIRECTED TO THE API AND FINISHED DOSE MANUFACTURING 8 **DEFENDANTS** 9 Mitchell H. Cohen Building & U.S. Courthouse 4th & Cooper Streets Camden, New Jersey 08101 10 December 11, 2019 Commencing at 10:05 a.m. 11 12 THE HONORABLE JOEL SCHNEIDER, BEFORE: 13 UNITED STATES MAGISTRATE JUDGE 14 APPEARANCES: 15 MAZIE SLATER KATZ & FREEMAN, LLC 16 BY: ADAM M. SLATER, ESQUIRE 103 Eisenhower Parkway 17 Roseland, New Jersey 07068 For the Plaintiff 18 GOLOMB & HONIK, P.C. BY: RUBEN HONIK, ESQUIRE 19 DAVID J. STANOCH, ESQUIRE 1835 Market Street, Suite 2900 20 Philadelphia, Pennsylvania 19103 For the Plaintiff 21 22 23 Carol Farrell, Official Court Reporter cfarrell.crr@gmail.com 24 856-318-6100 25 Proceedings recorded by mechanical stenography; transcript produced by computer-aided transcription.

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APPEARANCES (Continued):
 1
 2
         KANNER & WHITELEY, LLC
         BY: CONLEE S. WHITELEY, ESQUIRE
 3
              LAYNE HILTON, ESQUIRE
         701 Camp Street
 4
         New Orleans, Louisiana 70130
         For the Plaintiff
 5
         KIRTLAND & PACKARD LLP
         BY: BEHRAM V. PAREKH, ESQUIRE
 6
         1638 South Pacific Coast Highway
 7
         Redondo Beach, California 90277
         For the Plaintiff
 8
         LEVIN PAPANTONIO
 9
         BY: DANIEL A. NIGH, ESQUIRE
         316 S. Baylen, Suite 600
         Pensacola, Florida 32502
10
         For the Plaintiff
11
         FARR LAW FIRM
         BY: GEORGE T. WILLIAMSON, ESQUIRE
12
         99 Nesbit Street
13
         Punta Gorda, Florida 33590
         For the Plaintiff
14
         RIVERO MESTRE LLP
15
         BY: JORGE A. MESTRE, ESQUIRE
         2525 Ponde de Leon Boulevard, Suite 1000
16
         Miami, Florida 33134
         For the Plaintiff
17
         DUANE MORRIS LLP
              SETH A. GOLDBERG, ESQUIRE
18
              JOSEPH S. FERRETTI, ESQUIRE
19
              REBECCA E. BAZAN, ESQUIRE
         30 South 17th Street
20
         Philadelphia, Pennsylvania 19103
         For the Defendants, Prinston Pharmaceuticals,
         Solco Healthcare U.S. LLC, and
21
         Zhejiang Huahai Pharmaceuticals Ltd.
22
         PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI LLP
              CLEM C. TRISCHLER, ESQUIRE
23
              FRANK H. STOY, ESQUIRE
         One Oxford Centre, 38th Floor
24
         Pittsburgh, Pennsylvania 15219
25
         For the Defendant, Mylan Pharmaceuticals Inc.
```

```
A P P E A R A N C E S (Continued):
 1
 2
         GREENBERG TRAURIG LLP
             VICTORIA DAVIS LOCKARD, ESQUIRE
 3
              BRIAN H. RUBENSTEIN, ESQUIRE
              STEVEN M. HARKINS, ESQUIRE
 4
              DAVID E. SELLINGER, ESQUIRE
         3333 Piedmont Road, NE, Suite 2500
 5
         Atlanta, Georgia 30305
         For the Defendants, Teva Pharmaceutical Industries Ltd.,
 6
         Teva Pharmaceuticals USA, Inc., Actavis LLC,
         and Actavis Pharma, Inc.
 7
         HARDIN, KUNDLA, MCKEON, POLETTO & POLIFRONI, PC
 8
              JANET LYNN POLETTO, ESQUIRE
              ROBERT E. BLANTON, JR., ESQUIRE
 9
         673 Morris Avenue
         Springfield, New Jersey 07081
         For the Defendant, Hetero USA Inc.
10
11
         CIPRIANI & WERNER, P.C.
         BY: JESSICA M. HEINZ, ESQUIRE
12
         450 Sentry Parkway
         Blue Bell, Pennsylvania 19422
13
         For the Defendants, Aurolife Pharma LLC
         and Aurobindo Pharma USA, Inc.
14
         KIRKLAND & ELLIS LLP
15
         BY: BRITTNEY NAGLE, ESQUIRE
         601 Lexington Avenue
         New York, New York 10022
16
         For the Defendants, Torrent Pharma Inc.
17
         and Torrent Pharmaceuticals Ltd.
         FALKENBERG IVES LLP
18
         BY: KIRSTIN B. IVES, ESQUIRE
19
         30 N. Lasalle Street, Suite 4020
         Chicago, IL 60602
20
         For the Defendants, Humana, Inc., and
         Humana Pharmacy, Inc.
21
         DRINKER BIDDLE & REATH LLP
22
         BY: MICHAEL C. ZOGBY, ESQUIRE
         600 Campus Drive
23
         Florham Park, New Jersey 07932
         For the Defendant, Express Scripts
24
25
```

1	APPEARANCES (Continued):
2	BARNES & THORNBURG LLP
3	BY: SARAH JOHNSTON, ESQUIRE 2029 Century Park East, Suite 300
4	Los Angeles, CA 90067 For the Defendant, CVS Pharmacy, Inc.
5	ULMER & BERNE LLP
6	BY: JEFFREY D. GEOPPINGER, ESQUIRE 600 Vine Street, Suite 2800
7	Cincinnati, Ohio 45202 For the Defendant, Amerisourcebergen Corporation
8	NORTON ROSE FULBRIGHT US LLP
9	BY: ELLIE NORRIS, ESQUIRE DLESCI DAVIS, ESQUIRE
10	2200 Rose Avenue, Suite 3600 Dallas, Texas 75201
11	For the Defendant, McKesson Corporation
12	
13	
14	
15	
16	
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(PROCEEDINGS held in open court before The Honorable Joel
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    Schneider, United States Magistrate Judge, at 10:05 a.m.)
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             THE DEPUTY CLERK: All rise.
             THE COURT: Good morning, everyone. Please be
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    seated. Welcome back to Camden.
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             We are on the record in In Re: Valsartan. 19-2875
 7
   is the docket number.
 8
             Can we just have the entries of appearance of the
   lead counsel.
 9
             MR. NIGH: Daniel Nigh for the plaintiffs.
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             MR. SLATER: Good morning, Judge. Adam Slater for
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   plaintiffs.
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13
             MR. HONIK: Good morning, your Honor. Ruben Honik,
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   plaintiffs.
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             MS. WHITELEY: Good morning, your Honor. Conlee
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   Whiteley for plaintiffs.
             MR. GOLDBERG: Good morning, your Honor. Seth
17
    Goldberg on behalf of the ZHP parties and the Joint Defense
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19
   Group.
20
             MR. RUBENSTEIN: Good morning, your Honor. Brian
   Rubenstein on behalf of the Teva defendants and the Joint
21
22
   Defense Group.
23
             MR. TRISCHLER: Good morning, your Honor. Clem
24
   Trischler on behalf of Mylan Pharmaceuticals and the Defense
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   Group.
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THE COURT: So this was the conference that was scheduled, I believe, in the August 26th order where we were going to decide and address all discovery disputes.

The Court's goal, when we leave the conference today, is to resolve all objections regarding the plaintiffs' document requests and, in a matter days, to get a hard copy of those documents requests. The Court will order that they have to be responded to without objections, we'll discuss when they have to be responded to, as well as identify all of the custodians and search terms for the API and finished dose manufacturing defendants, and similar to what we did in Benicar, we'll document that in a Court order so that there's no misunderstanding or confusion about what's required.

I read all the parties' papers. I understand there are some miscellaneous issues. I would have liked to avoid the December 18th conference, like we discussed. It does not appear that to be the case, although I hope I'm wrong. I'd be delighted if we could resolve everything today.

What I plan for today -- and I'll, of course, address any issue that defendants and plaintiffs, of course, want to address -- is: One, you'll get the Court's ruling on the redaction issue that the Court raised; then we'll address plaintiffs' document requests, and address all of the objections, and hopefully get them resolved; then we'll do the custodian issues; then we'll do the search-term issues; and

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then we'll open up the floor to whatever the parties want to talk about; and, hopefully, we'll leave today with some semblance of a schedule about when these documents are going to be produced -- rolling basis, substantial production, what have you. I read the parties' papers in detail. I commend the parties for their what appears to be substantial recent efforts to meet and confer. I am not of the mindset that just because there's disputes, it doesn't mean the parties didn't engage in good-faith discussions. I do believe that the parties can have reasonable disputes, even if they exhaust good-faith efforts to try and resolve their disputes, and that's what we're here for. We'll resolve those disputes. But it's painfully obvious to the Court that a lot of time and effort was spent on these issues, and I commend the parties for that. And, as I've said from the beginning, I believe that this is the most labor-intensive part of the case, trying to get the document production, ESI production underway, and once we get through this, I think we should have smooth sailing for the rest of the case. But my experience tells me this is the most problematic part of a complex case, dealing with the ESI issues, especially in this case, dealing with foreign language and foreign defendants. So I want to start out by giving you the Court's

ruling on the redaction issue before the Court, and I'll

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confirm the Court's ruling in an order to be entered. So let me give you the Court's oral opinion.
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The redaction issue to be decided was raised by the Court after it received the parties' recent letters addressing the parties' macro discovery disputes. After reading the submissions, the Court asked the parties to brief the issue of whether defendants' redactions of their core documents was appropriate. This oral opinion will serve as the Court's ruling on the issue, to be confirmed in an order to be entered.

By way of brief background, on April 29, 2019, the Court identified what it denominated "core discovery" the API and finished dose manufacturer defendants should produce.

"Core discovery" was defined as discovery that was: One, easily identifiable; two, unquestionably relevant and not privileged; three, relatively simple to retrieve, and four, discrete. The purpose of the early production was to assist the parties to identify the genuine issues in dispute and to assist the parties to timely frame an acceptable ESI protocol. The documents largely consisted of communications between defendants and the FDA.

When produced, the documents were redacted by the defendants for what they deemed to be irrelevant and nonresponsive information.

Plaintiffs object and argue they should receive

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complete or unredacted copies of defendants' core documents.

To assist the Court in its decision, the Court asked the parties to identify 20 representative documents that the Court would review in camera to decide if defendants' redactions were appropriate. Fortunately, the parties agreed on 20 representative documents which were reviewed by the Court in camera.

The Court rejects the notion that it is premature to address this redaction issue. The issue was raised by plaintiffs in their letter briefs, and the Court will not delay addressing a discovery dispute that has the potential of hampering the efficient operation of the discovery process.

After reviewing the documents in camera, these are the Court's general impressions:

- (1) There were no redactions regarding valsartan.
- (2) All redactions were to public documents that plaintiffs could get themselves from the FDA.
- (3) Some redactions prevented plaintiffs from fully comprehending what was produced.
- (4) Frankly, it does not appear to the Court that "clearly relevant information" was redacted; however, the Court is not prepared to rule that only irrelevant information was redacted because it is not privy to the same information plaintiffs have, and it does not know the ins and outs of plaintiffs' theory of the case.

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Given the interests at stake and largely based on its in-camera review, and also on the fact that the Court's ruling only applies to the discrete set of defendants' core documents, the Court will order defendants to produce unredacted copies of all core documents. This includes removal of the FDA's redactions in the documents if the defendants have full and complete copies of those documents.

The Court's reasons for its ruling are as follows:

- (1) The core documents we are talking about may be the most important documents to be produced in the case. Plaintiffs should make the determination for themselves whether certain information in these critical documents is or is not relevant.
- (2) Since we are talking about FDA or publicly accessible documents, plaintiffs have access to the documents at issue. It makes no sense to require plaintiffs to make an independent request for documents already in defendants' possession.
- (3) When the Court ordered production of core discovery, it did not contemplate they would be redacted.
- (4) If the information that was redacted is genuinely irrelevant, defendants will not be prejudiced.

It is unquestionably the case that some redactions have to be removed because, otherwise, plaintiffs can't understand the full context of the documents they received.

The Court does not want to be bogged down in a document-by-document analysis of whether redactions are appropriate.

To the extent defendants are concerned about producing HIPAA information, they are protected because the production is pursuant to Court order.

Further, the Court assumes the documents at issue have been designated confidential pursuant to the DCO, the discovery confidentiality order.

Despite the fact the Court is ordering the production of complete copies of defendants' core documents, the Court is not -- repeat "not" -- ruling at this time that redactions of defendants' other documents to be produced are off limits.

Redactions of genuinely irrelevant material is permitted, with the proviso that they must be accompanied by an indication of why the redactions are being made. This doesn't have to be done on a document-by-document basis, but can be done by category.

The Court adds that if the redaction issue becomes a problem in the future, the Court will revisit defendants' permission to redact. The Court assumes defendants will only redact unquestionably irrelevant material and, in the Court's words, "sharpen their pencil."

On the other hand, the Court assumes plaintiffs will use good judgment if they make an application to challenge a

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redaction. If plaintiffs' applications are made without good
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    cause, the Court may bar challenges in the future.
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             For quidance on this redaction issue, the Court
    refers the parties to the Special Master's R&R, adopted by
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   Magistrate Judge Goodman in Communications LLC v.
 5
    Intellisphere, 2017 Westlaw 3668391, District of New Jersey,
 7
   April 25th, 2017. There the Special Master stated that "Only
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    the presence of unique circumstances should necessitate the
    Court's involvement with redactions for nonrelevant
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    information." The Special Master encouraged the parties to
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   meet and confer on any disputes and resolve the disputes
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    without bringing the issue to the attention of the Court.
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             The same instruction applies in this case. It is
    true that the Special Master in that case ruled that,
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    generally, redactions are not authorized; however, at this
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    time and under the present circumstances, this Court will not
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    go that far. If, however, defendants' redactions are
    unnecessary, excessive, or inappropriate, the Court will not
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   hesitate to bar all redactions.
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             That's the Court's ruling, counsel.
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             I think my order that I drafted puts a date of
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   production of January 31st. I assume that gives the
    defendants enough time to produce the documents, but if there
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    is a problem, just let me know.
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             You're looking at me, Mr. Goldberg, like you have a
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   question.
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             MR. GOLDBERG: One thing to clarify about the FDA
    documents that the Court has ordered --
             THE COURT: I know what you're going to say. Here is
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   my position on that. I may not have been as clear as I should
   have been.
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             I understand that documents that the FDA sent to the
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    defendants may be redacted. If the defendants don't have
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    complete copies, obviously, they do not have to produce
    complete copies. I understand that. What I'm -- what I was
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    referring to is situations where a redaction may have been
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   made in the documents, but the defendants have complete copies
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    of the documents. If the defendants have it, produce it.
   But, obviously, if the redactions are made by the FDA and the
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    defendants don't have what's underneath the redactions,
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    clearly, they don't have to produce it. If the plaintiffs
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17
    want that, they'll have to go to the FDA and do what they have
            That's what I intended by the ruling.
18
    to do.
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             MR. GOLDBERG: (Nods head.)
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             THE COURT: Okay. So let's now turn to the documents
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    issue.
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             What the Court envisioned was to have a set of
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    document requests, attach them to an order, and say
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    these documents -- just akin to the fact sheets -- these have
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   been approved by the Court. No objections. This is when they
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have to be responded to.
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             I have the red line that Mr. Goldberg was kind enough
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    to send the Court. Is that the last -- the version we should
 4
   be working with?
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             MR. SLATER: I think it's the December 5, whatever --
    I think that was the last --
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 7
             THE COURT: Mine is dated December 2nd.
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             MR. SLATER: Right, but it was the one we submitted,
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    I think, with our briefs on the 5th. We have not changed it
    since then.
10
             THE COURT: Okay. So why don't we just go through
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    them one by one, and if there is an issue, we'll address it,
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13
    decide it, the language will be cleaned up, and we'll get a
14
    final version.
15
             So a good place to start is number one. Any
    objections? I will start with -- well, I guess we should go
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17
    to the defendants.
             MR. SLATER: No objections, your Honor. Next one.
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             THE COURT: Any objection to Number 1?
19
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             MS. NAGLE:
                        No objections, your Honor.
             THE COURT REPORTER: I'm sorry. I can't hear you.
21
22
             MS. NAGLE: Brittney Nagle on behalf of defendants.
23
             THE COURT:
                        Maybe she spoke too soon, Mr. Goldberg?
24
             MR. GOLDBERG: No, your Honor, I just want to
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    explain. The way we -- because of all the document requests
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and the way the parties have been working through this, there
 1
   have been plaintiffs' counsel that have handled certain --
 3
             THE COURT: Good.
             MR. GOLDBERG: -- and certain defense counsel that
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 5
   have handled it, so that's how we're planning to --
             THE COURT: No problem at all.
 6
 7
             Okay. Number two? Defendants, we'll have to hear
 8
    from you, and if there is an objection, then we'll go to the
 9
   plaintiffs.
             MS. NAGLE: Your Honor, defendants have no objection
10
    to Part A of Request 2, regarding executives. But we have an
11
12
    objection to Parts B and C or just C.
13
             THE COURT: Is there a problem -- I agree with you on
14
   С.
15
             MS. NAGLE:
                        Okay.
16
             THE COURT: I don't have a problem with C.
17
             But is it really a burden or problem to identify who
    is on the Board of Directors?
18
             MS. NAGLE: The only issue is we're not sure that all
19
   have that historical information like out in charts. We --
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             THE COURT REPORTER: I'm sorry. I'm having a very
21
22
    difficult time hearing what you're saying.
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             MR. GOLDBERG: I think the point on B is -- I think
24
    defendants' position is to the extent they exist, then the
   Board of Directors' names --
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             THE COURT: No problem.
 2
             MR. GOLDBERG: -- should be identified.
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             THE COURT: That goes for everything. So Number 2,
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   we'll strike subpart C, and leave A and B.
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             MR. SLATER: Could I ask for one small modification,
 6
   your Honor?
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             THE COURT: Sure.
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             MR. SLATER: And just to clarify one thing for the
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             We didn't only ask for organizational charts.
   asked for similar documents. We assume that the parties have
10
    something that documents who their board members were, whether
11
    it's an org chart or a list of Board of Directors.
12
13
             THE COURT: Wouldn't you just accept a list?
14
             MR. SLATER: Yeah, absolutely.
15
             THE COURT: Okay. Fine.
16
             MR. SLATER: And the only thing on C is the one
   narrow exception I would ask for is if an entity that is a
17
   party to this case has ownership of another entity, for
18
19
    example, we just want to know the full extent of the ownership
20
    of, for example, Solco or Princeton or Huahai by ZHP --
21
             THE COURT: Request denied.
22
             MR. SLATER: Thank you.
23
             THE COURT: Let's concentrate on the relevant issues.
24
             Number 3.
25
             MS. NAGLE: We have no issue with that.
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1
   plaintiffs.
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             We are asking for production of three, to our
 3
    knowledge, three additional regulatory files for unapproved,
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    tentatively approved, or withdrawn ANDAs, and two -- two ANDAs
 5
    and one DMF.
 6
             THE COURT: I read that. Request denied. If it was
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    a standalone request and we didn't have 115 other requests,
    your request might have some merit, but given the scope of
   what we're talking about, I think what you're asking for is
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    such an insignificant addition to the mammoth amount of
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    information that's going to be produced in this case, so
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    that's why the Court rules like it is.
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             Number 12?
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             MR. RUBENSTEIN: Again, I think the same goes for 11
    through 15, as long as it's for products that were sold within
15
    the United States, then I don't think we have any objections.
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    But I think to the extent they're asking for unapproved,
    withdrawn, or other applications, then we do have the
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    objection, but I believe you just ruled on that.
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                         I did.
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             THE COURT:
             MR. RUBENSTEIN: So, pending your ruling, then we
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22
    don't have any more objections.
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             THE COURT: Okay. So 11 through 15.
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             16?
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             MR. SLATER: Your Honor, one question.
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             THE COURT: Oh, I'm sorry.
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             MR. SLATER: Should we modify those to put in that
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    language? I understand the answer from them is going to be
    "none," but should we modify the request to say "for products
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    sold in the United States" just so that we have the record
    that --
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             THE COURT: I think that would be helpful, yes.
                                                              Yes.
 8
             MR. SLATER: Okay, thank you.
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             THE COURT: Number 16? Oh, document retention
   policies. This is an interesting issue. You know, I don't
10
    understand why this is not relevant, frankly. I read the case
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    law that you all cited, but I don't think you need to show
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    spoliation to get a company's document retention policy.
    They're going to ask -- they ask for relevant documents in the
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15
    case. Maybe, maybe not, sometime in the future, they'll say
    why wasn't this document produced because the document
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    retention program required that it still be in existence? I
    don't think it's a prerequisite to ask questions about a
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    company's retention program to have to show spoliation. I
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    agree, they haven't shown it yet. I ruled on that. But they
    have shown that there are questions about whether appropriate
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22
    and relevant records were destroyed. That may not be
    spoliation because at the time they were destroyed, they
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24
    didn't foresee litigation, at least on the present record, but
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    it just seems to me that it's obviously a relevant area of
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discovery. So the objection to 16 is overruled, and
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   defendants have to produce their retention or destruction
   policy. It just seems to me clear that that has to be
   produced. I was in practice for a long time, and that was
    always the case, so that's my ruling on 16. The objection is
    overruled.
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 7
             17?
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             MR. SLATER: 17 and 18 are withdrawn, your Honor, per
 9
   your indications to us --
             THE COURT: Good.
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             MR. SLATER: -- previously.
11
12
             THE COURT: 19?
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             MR. GOLDBERG: Your Honor, 19 through 20 -- 29, all
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    cover manufacturing. And we have pretty thorough -- you know,
    a pretty thorough list of documents that we've agreed to
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   provide. It's not -- I think there is not really a dispute.
16
17
    I don't know how you want -- if you want me to read those into
    the record or you want us to work with plaintiffs to create a
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19
    longer document request that calls these out?
             THE COURT: Well, I don't know how to handle this. I
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    agree with defendants that, as framed, the documents are
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    overbroad. They're not specific enough. So I don't know how
    to handle this, plaintiffs. Do we go one by one? Do we agree
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    that defendants are going to produce the categories that
25
    they've listed in their letter?
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MR. SLATER: I don't know that we can do that.
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 2
    think that -- I mean, we tried to narrow these requests based
 3
    on the content of the meet and confers, and we tried to narrow
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    it to what the parties had agreed to. I have no problem with
 5
    talking to the defense further and then --
             THE COURT: No, today is the day.
 6
 7
             MR. SLATER: No, I agree with you. I agree. Because
 8
    if we defer it to talk more, we could end up here if
 9
    there's an issue --
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             THE COURT: No, no, no more talking. We had since
11
   August to talk.
12
             MR. GOLDBERG: Your Honor --
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            MR. SLATER: I think we have to take our medicine
14
    today.
15
             MR. GOLDBERG: I can read these fairly quickly.
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             THE COURT: Is this from your letter, your December
17
    10 letter?
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             MR. GOLDBERG: Let me just see. I have it in bullet
19
   points.
20
             MR. SLATER: I think that was a little narrower than
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    what we're prepared to agree to. I think it might not take
22
    that long to go through these because --
23
             MR. GOLDBERG: I can read these and they can --
24
             THE COURT: Well, is it in your letter? Because I
25
   remember reading -- or it could be an attachment. I remember
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seeing a list of manufacturing-type documents that was --
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 2
             MR. GOLDBERG: That was a different -- that was a
 3
    letter prepared by Ms. Hilton, and then that led to further
    discussion, and so we have an agreement based somewhat on that
 5
    letter.
 6
             THE COURT: Page 4?
 7
             MR. SLATER: Judge, I think it makes sense for us to
8
   go request by --
 9
             MR. GOLDBERG: Your Honor -- yeah, and I -- yeah.
10
             MR. SLATER: It makes sense to go request by --
   because some of those listings, I think we should just get it
11
    straight, make sure we're all on the same page, because it may
12
13
   not impact some of the requests. Some of the requests, they
   may say yeah, we're going to give you that.
14
15
             THE COURT: Okay.
16
             MR. SLATER: Because ultimately your Honor wants to
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   attach a set to an order.
             THE COURT: Yes.
18
             MR. SLATER: So I don't think this will take that
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20
    long.
             MR. GOLDBERG: Why don't I read what I have and if --
21
22
             THE COURT: All right. You start and then we'll go
    to Mr. Slater.
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             MR. GOLDBERG: Okay. So --
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             MR. SLATER: For Number 19?
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peaks; documents regarding corrective and preventative action plans initiated over time related to the manufacturing of valsartan API; validation documents provided or shown to FDA during inspections; SOPs and/or management procedures for all steps of the valsartan process development and manufacturing operations, including deviations, stability studies, risk management, change control, change management, returns, reprocessing, chromatography, the keeping and maintaining of reserve samples, API sampling, complaints, returned products and recalls.

And then for finished dose: Documents regarding open DMF file documents received from the API manufacturers about their products; documents related to the qualification of vendors used to source raw materials, solvents, or provide solvent recovery services, including questionnaires, on-site audits -- any on-site audits conducted of the vendor's facilities; SOPs and/or management procedures related to raw materials and/or the maintenance of any equipment used in the manufacturing of valsartan API, including cleaning recovered solvents, raw materials and packaging materials, pest and rodent control, water purification systems, raw material sampling, and vendor selection and approval.

All of this for the -- for sale into the U.S. market, and, of course, subject to the Court's macro discovery rule.

That's where we are in 19.

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THE COURT: All right. Between 19 and 29,
Mr. Slater, is there anything else you want? I mean, are
there any other issues we should talk about that Mr. Goldberg
didn't list in his categories?
         MR. SLATER: If I could, I'd prefer not to just have
to pick it out. I would rather walk through item by item and
just confirm with them because there may be certain things --
         THE COURT: Okay.
         MR. SLATER: -- but I will say in broad stroke, my
sense of the approach, if your Honor is okay with this and if
the defense is okay, is through the meet and confer process,
that list was created to give us what we thought would be a
fairly thorough overview of the process. I mean, it covers,
we think, the most important things as we know them today and
as have been discussed openly in court; for example, what is
the overall process, what testing was done from the beginning,
how was the process developed, anything having to do with
solvents, reuse solvents, how they're used, how they're
tested, how they're --
         THE COURT: Agreed.
         MR. SLATER: So it sounds like -- and then there is a
broader reach to these documents, so our thought is, in
good -- to use the meet and confer process as intended, is to
say, okay, as to the overall manufacturing process, we're
willing to agree to that because that's the list that came
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from the discussions, with the caveat that if, through the
review of the documents, it appears that there is something
that just didn't come up, not through any -- there's just a
lot that we're covering -- that we can talk about it and add
to that list if it's not covered by these overall categories,
just so that we have that caveat, because, to a certain
extent, all the lawyers are in a little bit of a vacuum
because we haven't all looked at the documents yet. And then
I think, as a second step, if we can just briefly go through
the requests and just confirm whether or not -- if the defense
confirms yes, that's incorporated by those requests, and is
there anything missing, because there might be a few examples
of things that we might just have to pinpoint, that way, at
least we're on the same page when we walk out of here.
         THE COURT: All right. Let's do it.
         MR. SLATER: Okay.
         THE COURT: But I've said this so many times before.
We're going to set the search terms, the custodians, the
document requests, but if there is good cause on either side
to either add or subtract from what we agree to and order, the
Court will entertain the application. So if there is a
specific document or category of documents that are just
missed, and there is good cause to get it, you'll get it.
         MR. SLATER: Understood. We always worry about the
diminishing window of good cause as time goes on but --
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we want to make sure we capture that as to the important
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    ingredients in the process.
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             MR. GOLDBERG: I don't think there is an objection.
             THE COURT: So, just to clarify, when these requests
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    for documents are redrafted, are you going to take
   Mr. Goldberg's list and just add them to the document
 7
    requests?
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             MR. SLATER: I mean, I suppose one thing we could do
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    is just get the page of the transcript and -- we could do
    either one, you know. We will have to refer to the
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    transcript. Or, Mr. Goldberg, you know what? You could send
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    is to us and we can put it in. But my feeling was to actually
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    not do that, actually, is to just leave the request as is.
   But we're on the record saying that, as a first blush, we're
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    defining what's going to be produced, so that's in the record,
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    and if there is something we don't get and they say, well, we
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    didn't list it, then we would to have meet and confer on it.
             THE COURT: So could you put, maybe in parentheses
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    after 19, as listed or described by defendants at the December
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    11, 2019 conference, so at least we know where to go to if
    there is some issue with that?
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             MR. SLATER: Yes.
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             THE COURT: All right. Number 20 --
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             MR. SLATER: I think we just covered that.
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             THE COURT: Okay.
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MR. SLATER: 21, this is a question on testing, and your Honor, I assume, saw the letter we sent in. So it starts to implicate the testing issue. It doesn't sound like we have a terribly giant divide on it. I think the only divide on testing is our ability to just make sure we know what testing was done, the complete list, which your Honor ordered. We worked with what ZHP produced to us and you saw it and we provided your Honor a list of testing, and they have to confirm whether -- I think they're agreeing those tests would be produced, but I won't say that for them. So we're fine with it. I mean, certainly, we think this request encompasses all the testing we've asked for.

I don't know if there is still an objection, but we have to define what we're going to get, and I don't know if there is still a dispute on it because what we're still just asking for is the list because we appreciate them identifying what they identified in the documents. It got us ahead of where we were. But we also want to make sure we're just not missing something, and, frankly, we want to make sure that defense counsel also knows from their client this is the full list.

We're not going to ask for a test to make sure a box is watertight. We're not going to ask for things that are irrelevant. We just want to make sure we can at least show our experts, which we have in good faith done so far, the list

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and just say is there anything you see here that you would say
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   we need to find out more about that? That's really -- which
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   we have ordered previously, so, subject to that, we're -- I
    don't think there is an objection to this request. I'm
    speaking for them --
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             THE COURT: So, with regard to Number 21, I quess
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 7
    that's the issue before the Court, right? Is there an
 8
    objection to 21?
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             MR. SLATER: Right. And I quess -- I'm talking
    through as if they're not objecting so --
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             THE COURT: Well, we have to find out, don't we?
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12
             MR. GOLDBERG: It sounds like what you're asking for
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    now, Adam, is that, again, defendants just generate a list of
    all the tests, testing that we do.
14
             MR. SLATER: That's what was ordered, so, I mean, I
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    think that -- we just want to make sure we don't miss
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    something. If there is something material that, for some
    reason, we don't know about, that's just not going to help
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    anybody. So that was -- it was already previously ordered, so
   we think it should be done, just to make sure that we don't
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   miss something.
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             THE COURT: Well, clearly, if it's ordered, it has to
   be done. But the issue before the Court is Number 21.
23
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    there an objection to 21? Is all you're asking for in 21 is
   the list of the tests?
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MR. SLATER: No, we are asking for the documentation of the testing and the results.
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MR. GOLDBERG: And this is where it gets -- I mean, this is sort of where it gets far afield. We -- I think we generally agree that chromatography is the key type of test here. Mr. Slater's letter from yesterday identified, I think, that was -- primarily, those are different types of chromatography, and that's where their experts are going to be focused.

So we have walked through, at least from ZHP's standpoint, with plaintiffs, the information that demonstrates the different kinds of tests we do, including all of that chromotography. That's how the letter was generated. I understand that other defendants have provided similar information, pointing plaintiffs to the Bates numbers.

I don't think there is any dispute that we're going to be producing chromatography -- that was in that list I just gave you about 19 -- and all of the results relating to chromatography. And I think plaintiffs have very good lists about 99 percent of all the other kinds of tests that we do -- water, appearance, solubility, whatever it is -- and, you know, it seems that the likelihood that they're missing a test is very low.

If their experts can say to us, we expected to see a certain kind of test, or we -- or do you do this kind of test,

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maybe that would be helpful because they have a list of about
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    99 percent of the testing we do. And so --
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             THE COURT: I'm not sure where we are, frankly.
 4
             MR. SLATER: This is what I think, to try to recenter
 5
   it.
 6
             THE COURT: Because I don't want to be back here
 7
    arguing about Number 21. Let's resolve it now.
 8
             MR. SLATER: I will try to recenter it. And I think
 9
   part of the issue is that myself and Mr. Goldberg were
    talking, and we're talking in the context of ZHP, but there is
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   multiple defendants.
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12
             THE COURT: I understand.
13
             MR. SLATER: So ZHP gave us identification of testing
   within their core discovery documents, and we have the
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    December 10 letter defining -- we wrote back to them, after
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    consulting with our experts on that, saying these are the
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    tests that are described in those documents that we need.
    I would think that that list, if acceptable to the defendants,
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   would apply to all defendants. But the other defendants,
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   we're just starting to get references to documents from them.
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    We got one last night. We got one Monday. So it's not on an
22
    equal footing, all defendants, so that we have to remember
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    it's not just one defendant.
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             MR. GOLDBERG: Yeah --
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             MR. SLATER: There is a couple of other
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manufacturers.

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MR. GOLDBERG: Well, I mean, I think that's a good point. If that letter that you sent is representative of the kinds of testing that you really want to be produced and focused on, then let us talk about that, let's -- because I don't think the other defendants got that letter, unless it was attached to the brief. I don't know if it was. But that, again, is the different kinds of chromatography that could be at issue.

So, it seems to me that the question is: defendants agree that, for that set of tests or some subset of that long list, there is going to be a production? And do plaintiffs feel like they really need any other kind of testing? Because that's the chromatography testing that their experts have now identified as being the key types of testing.

MR. SLATER: I think I know where they are. We need the lists from all the defendants because we have to make -we don't know that they all do the same tests. And they may have run a certain test three times in 2017, some part -- one of the API's may have run that no one else did, that's not normally done, that could be very significant. So we just need to know that and it's already been ordered.

Our letter of December 10 to ZHP, if they say, well, we're not objecting to that and we're going to provide those, and all parties will provide that type of testing or similar

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testing, then at least we know they're not objecting to it and
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    they're giving it to us, but I would say that -- and we have
    it in the brief. Your Honor has our unredacted version of the
   brief which mimics the letter and what we said we want.
    all that was to show the Court is if they were objecting, we
    wanted the Court to know these are right in the wheelhouse of
 7
   what they said is relevant. But I think the requests should
 8
   be responded to and the list should be provided.
 9
             THE COURT: I want to phrase Number 21 in a manner
    that it's going to be Court ordered that has to be produced.
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   Now, right now it says, "any testing." Too broad. No good.
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    It has to be more specific.
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             MR. SLATER: Well the problem is this: We still
    don't have -- if you wanted us to list all of the particular
14
15
    tests, the problem is we don't have a list of what all the
16
   parties did.
17
             THE COURT: So would it be testing -- does this get
    into the macro issues that the Court decided? Would it be
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    testing that would reveal the presence of nitrosamine --
19
20
    however you pronounce it -- contamination?
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             MR. SLATER: Well, it would be testing that goes
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   beyond that because there could be -- there are tests that
    were not directed to identifying NDMA. It was only after the
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    disclosure of this issue that they started to do tests where
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they were looking for NDMA, for example. Before that, there

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were more generalized testing, from what we've seen so far,
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   mostly the different types of chromatogram, which would test
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             There is also separate testing for bioequivalency --
   purity.
             THE COURT: But Number 21 has to be phrased in a
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   manner that the Court is going to order it. That's what I'm
 6
    trying to get to.
 7
             MR. SLATER: Well --
 8
             THE COURT: And --
 9
             MR. SLATER: Now about -- and I'll leave it subject
    to my team -- testing capable of indicating impurity,
10
    contamination, or lack of bioequivalence -- and what Layne is
11
   pointing out is, there is really two types, there's testing of
12
13
    what they manufactured, and there is also testing, frankly, of
    the solvents before it's used in the process.
14
             So, again, that's why I'm trying to be broad because,
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    for example, our experts have pointed out and we've told them
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17
    in our letter, certain of this testing was of the solvents or
    the reused solvents, and we need to know those results from
18
    each of the parties that manufactured, because they're not
19
    going to say, oh, this is NDMA. What they're going to show is
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    peaks that shouldn't be there, and that's why we need the full
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22
    scale of testing to show you were seeing this, and then, all
    of a sudden, it looked like this.
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24
             THE COURT: Well, we have --
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             MR. GOLDBERG: Judge, we're now revisiting --
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THE COURT: I'm going in circles here.
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             MR. GOLDBERG: I'm afraid what is about to happen is
   a reconsideration of Decision 8 in the macro issue rulings.
             The Court ordered that plaintiffs are entitled to
 4
    discovery regarding any tests that could identify the presence
 5
    of nitrosamine contamination; also, testing and results
 7
    regarding other carcinogens, general toxic impurities, or
 8
    residual solvents in the valsartan API and valsartan finished
    dose is relevant.
 9
             And during that conference, your Honor was very
10
    clear, there's not going to be testing about water and testing
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12
    about color.
13
             THE COURT: So that definition should be incorporated
14
    somehow into Number 21. That's what I was referring to.
15
    So --
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             MR. HONIK: Your Honor, the way to do that,
17
    respectfully, might be -- the language currently reads:
    "Produce all documents, including photographs or video, with
18
    regard to any testing or inspections." We can insert there,
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    "for purity and contamination consistent with," and then refer
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    to that language, simply refer to it. And then it's further
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22
    qualified with, "of the machines, materials, substances
    utilized in the manufacturing process." So it captures that
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24
    ruling, and it confines the testing to testing related to
25
   purity and contamination.
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             MR. SLATER: And bioequivalence.
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             THE COURT: Any objection?
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             MR. GOLDBERG: I do have an objection to the term
    "purity" because the Court used the phrase "toxic impurities."
 4
 5
    I'm not an expert, but I think there may be impurities that
    are not toxic, that could be tested for --
 7
             THE COURT: We're using the macro language. So
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    incorporate the macro language, no more, no less, into Number
 9
    21.
        That's --
             MR. SLATER: We'll do it. I think one of the things
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   probably be helpful, your Honor, is when we draft this, before
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    the Court sees anything, we will send what we propose to
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13
    defense counsel, obviously, to make sure that we are both on
    the same page before the Court would get it.
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15
             THE COURT: Okay. But I don't want to revisit the
   macro issues. Testing was one of the big categories that we
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17
    dealt with. We spent a lot of time on it, and I don't want to
    revisit it.
18
             MR. SLATER: Your Honor, there is the one issue on
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20
    the time period. This is one of the categories of requests
    where we feel that a narrow exception should be made because
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22
    the testing done from the beginning would show what the
    chromatography looked like before they made changes in the
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24
   process, so our experts can then look and say, look, you had
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    this rating, and then you changed the process and, all of a
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sudden, this peak came up. That's significant. So we need to
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   be able to go back to the beginning so we have the testing
   history.
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             THE COURT: No, I agree with you that, in concept,
 5
   what you're saying is correct. But if I recall correctly, if
   we're talking about ZHP, I think they go back to 2010 or
 7
    20- --
 8
             MR. SLATER: 2007 actually.
 9
             THE COURT: Okay, 2007. So you'll get the tests
   before the change and you'll get the tests after the change.
10
    I don't see any reason why we have to change the relevant time
11
12
   period.
             MR. SLATER: Because there were two changes.
13
                                                           There
    is actually three -- I'm sorry.
14
15
             MR. GOLDBERG: The relevant time period for ZHP is
    January 1st, 2010. And --
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17
             THE COURT: Whatever is in the order.
             MR. GOLDBERG: That is --
18
19
             THE COURT: Yes, that's what my recollection is.
20
             MR. GOLDBERG: -- Paragraph Number 9 in the macro
21
    discovery issues sets the relevant time period. And this very
22
    argument was made in the context of the macro discovery
23
            This -- plaintiffs made the very same argument three
   weeks ago about manufacturing documents, testing documents,
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25
    the process before. And remember, Judge, they had proposed
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going back to 2007. That was their macro discovery issue.
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   And the Court was very clear -- come back later, show cause as
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    to why you need something, and you'll get it. But we're not
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    at that stage yet, and if the Court revisits the decision
 5
    today, three weeks after --
             THE COURT: I'm not revisiting that decision.
 6
 7
             I recall -- I think it's the 2010 date, that's why I
 8
    say it. But wasn't the key manufacturing change made after
 9
    2010, Mr. Slater?
             MR. SLATER:
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             MR. GOLDBERG: Yes.
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12
             MR. SLATER: No. I'll tell you why. Well, the
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    answer is a key change was made then, but there were two
   manufacturing changes. There was an original process, then
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    there was a change to -- I'm not going to go with the titles.
15
    There was a second process which occurred before 2010, and we
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    have produced -- we have shown the Court, and it's in
    documents that have been before the Court, in retrospect, they
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19
   have gone back and tested. There was nitrosamines, there was
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   NDMA already showing up after the first manufacturing change
    and before the third one. The defense keeps talking about the
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22
    change that they made, the last one, but there was NDMA per
23
    the testing they have produced before that change.
24
             So what we need to -- when your Honor made your
25
    ruling, you said, look, this is my broad ruling, but if there
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are specific narrow categories where it makes sense, and this is the time, frankly, this one makes so much sense because when they had their first process, starting in '07, and they're testing it and they're running it, they're getting certain chromatography, peaks, you know, it's almost like a vital sign sheet.

And then they switch to the second process, and it changes. And someone needs to ask, well, what's happening here?

And then they get to their third process, and there's changes, but they need to compare it to the second and the original. And for our experts, it's very important, because there is no secret, part of our theory is when they made these changes, they needed to foresee that these chemical reactions could create nitrosamines. And they -- and we're going to see the documents to see if anybody was saying, hey, this is something we have to be concerned about. We have to look at this. Oh, these peaks are changing with the first manufacturing change. Why is that?

And when we have all the documents, we will be able to put together a picture, from the beginning to the end, and be able to, if we have to try this case, show the jury how things changed over the years and say, well, if this was -- this was concerning. If our experts say, you know what? Someone needed to look at that because if you look back on it

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now, if they had done this and this afterwards, they would have seen it was nitrosamines, but they didn't do that, and that was 2009 or that was 2011 or it was 2012. So if we don't have the entire sequence of testing, we can't do that, and we are severely prejudiced.

MR. GOLDBERG: Judge, this is -- this is exactly the argument that was made three weeks ago, and it was made as to every defendant, that there were things they needed before the relevant time period that your Honor had then set. this for every defendant -- Judge, we need to go back further. We need to go back to 2005 as to Mylan, 2007 as to Torrent. And the Court set relevant time periods because at some point there has to be a limit. We're talking about now nine years' worth of data. And the process issues that they're raising are not the process issues that are -- that have resulted in the recall, that have resulted in the NDMA, that are at issue. And it seems that your Honor's ruling that they can come back and ask for a specific document or type of document, here now they're asking again to sort of blow it wide open without specificity. So if during the discovery they realize, well, we really need to understand this part of the process predating 2010, then that's an issue they can raise. But they're not raising that specific issue now. Or if they get in the ten years' worth of documents something that suggests, you know, there is a reference to a deviation report from

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2009; of course they're going to get that deviation report.
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   But to revisit the ruling now would require us to look at
 3
    everything else again.
             MR. SLATER: Let me make it easy. The testing that
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   we identified in the letter from the documents they produced,
    in the first instance, we would agree to those tests going
 7
   back to the beginning, and then we can see what we get and we
 8
    can see if we have to come back. But without these tests, the
 9
    chromatography going back to the beginning, we can't do what
    we need to do to prove our case because we have to be able to
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    show the history and show the different time points when they
11
   missed what they should have been investigating further.
12
13
    ties our hands on an important part of the proofs.
             THE COURT: When will you be alleging that ZHP's API
14
    was contaminated with chemicals?
15
             MR. SLATER: Their documents show that it was
16
17
    contaminated with NDMA going back even before the last process
    change because they produced test results showing that.
18
19
             THE COURT: What year?
             MR. SLATER: 2009, I believe.
20
                         Okay. So isn't the -- and the relevant
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             THE COURT:
22
    time period is 2010 that was defined in the order?
23
             MR. SLATER: Yeah. I'm not sure what they're
24
    concerned about because these are the tests that they have
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    told us are the most important tests. So we're saying for
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this stage, we'll agree as to these tests that we bulleted in
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    our letter and your Honor has it in the brief, let's go back
 3
    to the beginning with those tests. If we need to ask for
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    something else, we'll be in the good cause shrinking window.
 5
             THE COURT: But they're arguing about relevant time
 6
   period, not necessarily about the tests, right?
 7
             MR. SLATER: Well, they've already agreed to produce
 8
    these tests.
 9
             THE COURT: Right.
             MR. SLATER: The only question is do we get them
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    going back to the beginning, and I don't think there is any
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12
   burden to this and --
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             THE COURT: The beginning is when?
             MR. SLATER: I believe they started the manufacturing
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15
   process in 2007. But they have these tests. What's the
   burden for them to produce them? And the prejudice to us
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17
    could be immense.
18
             THE COURT: So are we only talking about 2007 to 2010
    for ZHP?
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             MR. SLATER: Remember -- yeah, we're talking about
         We want to go back to the beginning for these tests or
21
22
    their compatriots with the other API manufacturers, but we
23
    only have the context of the dates with ZHP.
24
             MR. GOLDBERG: In other words, your Honor, if you
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   rule on this, then they're going to ask the same thing of
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Mylan and the same thing of Torrent, and this is a slippery
 1
    slope here.
 3
             THE COURT: It is.
             Would the earlier test results be encompassed within
 4
 5
    the Court's macro discovery rulings?
 6
             MR. SLATER: I believe that the macro discovery
 7
    ruling specific provided for narrow exceptions to be made as
   needed. That's what your Honor said. This is a clear one.
 9
             Look, if they're worried about the other defendants,
   we'll start with ZHP and then when we go through it -- but we
10
    can't -- here is the thing.
11
12
             THE COURT: No, my question was this. My Deputy is
13
    getting a copy of the order.
14
             Does the -- I don't recollect. Does the macro
    discovery order say you have to produce any document, anytime,
15
16
    anywhere in the world that reveals this chemical
    contamination?
17
             MR. SLATER: I don't believe so, because I don't
18
19
    think it was phrased that way. And I think this was one -- I
20
    think your Honor -- obviously, I'm speaking for you, so you
    can tell me, "You're all wet."
21
22
             I thought that the intent was, from the order and
    from the argument, look, this is the overall default time
23
24
   periods. But you acknowledged there may be certain narrow
25
    issues where we need to go back further. This is a critical
```

one, because, again, I'm not really sure why they're even objecting. They have the test results. They can't throw them in the garbage. They have to maintain them. They're not allowed to destroy them. So they have them. And, again, it's going to show the historical pattern of the results of what they have told us are the most critical tests, and for purposes of this ruling, we're agreeing to that, as of today, that we will run with that, and if something else comes up, we can come back. But taking at face value what they have told us, they have told us this is the testing that's necessary, so we're taking that at face value in the context of what we're asking for today.

THE COURT: Bear with me.

MR. SLATER: I mean, they're not telling you they don't have them. They're not telling you they can't find them. If they were to say that, that would be a real problem for the company, to say we can't find test results. So they have them.

THE COURT: So Paragraph 8 of the macro discovery order, November 25th, 2019, says: "Plaintiffs are entitled to discovery regarding any tests that could identify the presence of nitrosamine contamination. Also, testing and results regarding other carcinogens, genotoxic impurities, or residual solvents in the valsartan API and valsartan is relevant."

So, the question is whether that language is limited

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by the relevant time period set forth in Paragraph 10, right?
 1
 2
             MR. SLATER: I think that that's part of the
 3
    question. I think that the question after the semicolon is:
    If it were to be read that way, would it make sense in this
 5
   narrow context to say no, this goes back to the beginning,
   because that plaintiffs need that and there is no burden to
 7
   produce it. I mean --
 8
             THE COURT: Mr. Goldberg, I don't remember
    specifically -- I remember, obviously, the discussion about
 9
    the relevant time period. I don't remember ruling that this
10
    issue of the testing results and the different changes to the
11
   manufacturing process are off limits. I don't remember that.
12
13
   But I do remember, of course, setting the time period.
14
             MR. GOLDBERG: Well --
15
             MR. SLATER: I'm sorry. Just so you know, what I'm
    going to say, also, one of the things we're going to learn is
16
17
    also when did they do these tests? Maybe they didn't start
    doing a certain test until 2009 or 2010, but we have to also
18
19
    see what they were doing.
20
             MR. GOLDBERG: Your Honor, the language in Paragraph
    10 is the language that gets them documents that would predate
21
    the relevant time period. You see, it says, "This designation
22
    is without prejudice to plaintiffs' right to request older
23
24
    specific documents or categories of documents upon a
25
   showing" --
```

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1
             THE COURT: Upon a showing of good cause.
 2
             MR. GOLDBERG: And what I'm saying to your Honor is,
 3
   at least at this point, how could cause be different today
 4
    than it was three weeks ago? And they're making the same
 5
    argument --
 6
             THE COURT: No, no, no. I don't think we argued
 7
    these tests --
8
             MR. GOLDBERG: Yes, they argued everything --
 9
    everything before 2010.
             THE COURT: And I denied that.
10
             MR. GOLDBERG: Right.
11
12
             THE COURT: I still deny it.
13
            MR. GOLDBERG: And subsumed in everything are these
14
   tests.
15
             THE COURT: But we didn't specifically discuss these
    tests, did we? Because --
16
             MR. GOLDBERG: Yes.
17
             THE COURT: -- last time we were together, we didn't
18
19
   know what tests.
20
             MR. GOLDBERG: Yes, we did. We specifically
21
    discussed chromatography, specifically. And your Honor was
22
   very clear, and plaintiffs are on the record, we generally
23
    came to the understanding that chromatography is at issue, and
24
    that was subsumed in the ruling. And --
25
             THE COURT: Mr. Goldberg, plaintiffs are arguing,
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rightly or wrongly -- I don't know who's right -- that there
 1
   may have been contamination in ZHP's API as early as 2007.
 3
   How then can I deny them the right to get testing results
 4
    going back that far? How can I do that?
             MR. GOLDBERG: We haven't been presented with that
 5
    information.
 6
 7
             MR. SLATER: No, wait. I said 2009, you produced it
 8
    to us.
 9
             MR. GOLDBERG:
                           Well, where is it?
             MR. SLATER: It's in your core discovery documents.
10
             MR. GOLDBERG: Where is it?
11
12
             MR. SLATER: I'm sorry. Do you want me to whip it
13
    out of my pocket right now? Look, I have a team here that
   will find the document in the next five minutes or so.
14
15
             They produced the documents to us that showed testing
    showing NDMA prior to the manufacturing change that they keep
16
17
   pointing to.
18
             THE COURT: You want to go back to 2007 or --
19
             MR. SLATER: Yes.
             THE COURT: Why 2007 and not 2009?
20
             MR. SLATER: For a few reasons. One, for the tests
21
22
    that they've identified -- and I'm agreeing at this stage to
    limit it to this group of tests that we bullet pointed based
23
24
    on their representation this is the key core set of testing.
25
   And based on consultation with our experts, which has only
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happened in this last five days to six days, that this way we
 1
 2
    can show, A, which tests did they do, because I don't know if
 3
    they all these testing going back to 2007, and there may
   become an issue where they started to do a particular test
 5
   because they saw something and got concerned. We need to see
 6
    that.
 7
             THE COURT: So you think there is documentation or
 8
    evidence that contamination existed at least as early as
 9
    2009 --
             MR. SLATER: Yes, it's been produced.
10
             THE COURT: -- but you are pursuing and investigating
11
    whether it went back to 2007?
12
13
             MR. SLATER: And most importantly, let me tell you
        Let's assume it wasn't. Let's assume it started with
14
    whv.
   process Number 2. The appearance of those chromatograms
15
   before they made a change that then led to NDMA contamination
16
17
    is critical in terms of notice to the people in that Quality
    Assurance Department that they should have recognized we're
18
    seeing different findings, and we know from the documents,
19
20
    from what they were telling the FDA, they were explaining them
    away as ghost peaks, that they -- and the documents that we've
21
22
    seen show they did not adequately investigate those.
    swept them under the rug and moved on. And that's a big
23
24
    issue, that they didn't follow up on those.
             So let's assume it was clean from '07 to '09. That
25
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set of test results, that base set, is going to be put up in
 1
 2
    front of the jury next to the results that start to show these
    ghost peaks or artifacts, whatever you want to call them, and
    where our experts are going to say, yeah, this was the NDMA
 5
    starting to show up, and they didn't do what they needed to
    do. All they had to do was these standard tests and they
 7
   would have seen this is what it is. And so that's why we need
 8
    it, for those two reasons, your Honor.
 9
             THE COURT: What's the letter you've waiving around?
   What's the date of it?
10
             MR. SLATER: This is the Magna Carta -- no.
11
12
             This is the letter we wrote to Mr. Goldberg, December
13
    10, and the bullet points are in our brief to your Honor.
             THE COURT: And you list in that letter the tests
14
15
    that you want, the limited tests that you want?
16
             MR. SLATER: Correct. And the genesis of it, just so
    it's very clear for your Honor and for the record, is instead
17
    of giving us a list, what they did is they sent us a letter --
18
    I'm talking about ZHP because that's who we're talking about
19
    right now -- that said in the core documents, by Bates number,
20
    these are where the tests are that matter.
21
22
             We took that list, we took those documents, we went
    to our experts, and they looked at it. And, based on those
23
24
    consultations, we picked out of those documents the list of
25
    tests that they told us was relevant testing, and said this is
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what we need, and it's in the brief that we submitted
 1
 2
    yesterday, and it's in my December 10 letter to counsel, which
    they have agreed to produce all of those testing results.
             THE COURT: So tell me if this is the issue the Court
 4
 5
   has to decide: Whether ZHP has to produce, going back to
    2007, the test results for the tests that are described in
 7
    your December 10 letter?
 8
             MR. SLATER: Yes.
             THE COURT: That's the issue.
 9
             MR. GOLDBERG: With the caveat, your Honor, that they
10
    sent us that list yesterday, and we have not had the
11
    opportunity to even discuss whether all 15 of those kinds of
12
13
    tests are capable -- are the tests at issue. Yes, we have
    discussed chromatography, and those kinds of tests are
14
15
    chromatography tests.
             THE COURT: Are you representing, Mr. Slater, that
16
17
    the list in the December 10 letter was prepared in
    consultation with your expert?
18
19
             MR. SLATER: Absolutely.
20
             THE COURT: Okay.
             MR. SLATER: And I was involved in some of those
21
22
    consultations personally.
23
             THE COURT: All right. The Court finds -- I don't
24
   have any choice on this issue. If that's plaintiffs' theory
25
   of the case, I have to find good cause for ZHP to produce back
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to 2007, outside the defined relevant time, the test results
 1
 2
    for the tests described in plaintiffs' December 10, 2019,
 3
    letter. Somehow, you're going to have to incorporate that
    into the document requests.
 5
             MR. SLATER: We'll find a way.
             THE COURT: I mean, that's the kind of limited,
 6
 7
    discrete good cause that we're looking for. We're not
 8
    expanding the entire relevant time period for ZHP, but just
 9
    for this one specific category. Yes, the Court recalls
    extensive argument regarding relevant time period; but no, the
10
    Court does not recall a specific argument regarding this test
11
    result. It just seems painfully obvious to the Court that
12
13
    this has to be good cause if this is plaintiffs' theory of the
    case, rightly or wrongly, they have a right to pursue it, and
14
15
    the evidence will, you know, be what it is.
16
             MR. GOLDBERG: Your Honor, I'm not -- your Honor has
    ruled, but the transcript -- Mr. Honik saying that, three
17
    weeks ago. It began process one, 2007, September.
18
19
    when they started to introduce the ingredient, the recipe to
20
    their pills. We have already seen it, albeit not a lot, but
21
    we have already seen peaks from testing they have produced to
22
   us that goes back to that time frame. And your Honor then
23
    ruled, notwithstanding that very language, that very argument,
24
    on 2010. Your Honor has ruled. But ...
25
             THE COURT: Let's go on. What's next?
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MR. SLATER: The next one is 22, and I will ask
Mr. Goldberg. This is basically the same question as 19, but
it has to do with finished dosage formulation versus API.
We're willing to rely on the same list at this point in time,
so that it doesn't need to be changed. We can put in the same
caveat that your Honor had told us for 19, to say as described
at today's conference, if that's acceptable to everybody.
         MR. GOLDBERG: The finished dose list, I actually
read something about finished dose. It wasn't in that list --
         MR. SLATER: It was incorporated in the list. I was
just going to use the same language as referenced, as part of
what you stated. Is that okay?
         MR. RUBENSTEIN: At the macro discovery conference a
few weeks ago, you ruled that discovery into the finished dose
manufacturing process is not going to be nearly as extensive
as into the API. I mean, we submit that the manufacturing
process for the finished dose is all contained in the ANDA,
and I don't know what more they need that's outside of the
ANDA for the finished dose.
         THE COURT: We're talking about test results, though.
         MR. RUBENSTEIN: No, not anymore. At least --
         THE COURT: Is there anything in 22 that you want
that's not in the ANDA?
         MR. SLATER: Well, whatever they did after they
implemented the process -- did they do testing, did they do
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analysis, did they have inspections, certificates of analysis,
those types of things, when they implemented, which would be
part of the manufacturing process, if they tested the -- if
they tested the drug for purity, et cetera. It would be
things like risk assessments, if they did any; deviation
reports, if they did any; out-of-trend or out-of-spec reports,
if they did any; change requests, if they had them. That's in
the manufacturing process. So it's focussed on the specific
issue which is -- yes, essentially, it's the quality assurance
process that they implemented as -- in conjunction with the
manufacture of the finished doses. We're not, again,
interested in seeing how they folded the boxes together, taped
the label on.
         THE COURT: It's hard to argue that's not relevant.
         MR. RUBENSTEIN: And your Honor ruled at the last
conference the testing of the incoming API, which we have
already agreed to produce; the testing of the finished dose
materials. To the extend there are any changes, that would be
part of the FDA correspondence that goes along with the ANDA.
So, I mean, I think, in general, we're probably okay with the
list delineated by Mr. Goldberg. But --
         MR. SLATER: And we're fine with that at this stage.
         THE COURT: Okay. So you can work it out?
         MR. SLATER: I'm just going to put in the same
phrasing, unless -- and I will send it to them, if they have a
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problem with it -- saying as discussed today. And then I
 1
 2
    think we know what we're looking for. And if there is -- this
 3
    is the kind of thing I have to believe we can talk about as we
 4
    go through the document process. If there is a gap or
 5
    something, I don't think we need to bug you probably too much
    on something like this.
 7
             THE COURT: Good.
 8
             MR. SLATER: 23, it was a request that was changed
 9
   per your Honor's communication to us to just request those
    specific patents.
10
11
             THE COURT: Just the patents.
12
             MR. SLATER: If there are any. There may only be a
13
   few or none.
             MR. RUBENSTEIN: Your Honor, so patents on the
14
   machinery? I mean, that's -- I don't see how that's relevant.
15
    I mean, they're going to get the testing results.
16
17
             THE COURT: No, just the process, right? The
   manufacturing process you're talking about. You don't need
18
19
    the patents on the machinery.
20
             MR. RUBENSTEIN: Well, this says patents for any
21
   patented device, machine, or technology.
22
             MR. SLATER: We can drop the machine and the device.
23
             THE COURT: Just the patents for the manufacturing
24
   process.
25
            MR. RUBENSTEIN: To the extent there are any.
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1
             THE COURT:
                        I'm sorry?
 2
             MR. RUBENSTEIN: To the extent there are any, yes.
 3
             THE COURT: Yes, of course.
             MR. RUBENSTEIN: And then 24 talks about foreign
 4
 5
   patents, and I think your Honor ruled on the foreign
 6
    regulatory issue.
 7
             THE COURT: Right.
 8
             MR. SLATER: So 24 would be out?
 9
             THE COURT: Yes.
10
             Moving right along.
             MR. SLATER: 25 is just so we can identify third
11
   parties who were supplying the valsartan or what was used to
12
13
   manufacture the valsartan, and, obviously, we're most
    concerned with the solvents or reused solvents if they got any
14
15
    from someone else. Right. Putting the supply chain of the
    actual API going forward.
16
17
             MR. RUBENSTEIN: Okay. I guess that's for API. But
    for finished dose, you know, any ingredient, material,
18
19
    component, I mean, there is tons of inactive ingredients,
20
    excipients, that go into manufacturing finished dose. I don't
21
    see how any of that is relevant. I mean, you know, we can
22
   provide the --
23
             THE COURT: You have to work out the language.
24
   would assume you talked about this before we got here today.
25
             MR. GOLDBERG: We did, your Honor, and we really did
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come up with bullet pointed lists, and I'm afraid we're sort
 1
 2
    of muddying the waters a little bit now.
 3
             MR. SLATER: Yeah. I think that -- we just care --
 4
    as to a finished dose manufacturer, we just care where they
 5
    got the API because they're not dealing with solvents --
             THE COURT: Okay. Just clean up the language.
 6
 7
             MR. GOLDBERG: Yeah. No, that's fine.
 8
             MR. SLATER: Okay. But for the API manufacturers,
 9
    obviously, they did incorporate, for example, solvents into
    the process and other things, so it's more -- it's broader.
10
             THE COURT: 26?
11
12
             MR. SLATER: I mean, this would seem to be a very
13
    specific, narrow request. They are certificates of analysis,
    and we say similar documents, because someone may title it
14
15
    differently, but this is just -- I think it's encompassed
   probably already by Mr. Goldberg's overall representation, so
16
17
    I wouldn't think anything is objectionable about it.
             MR. GOLDBERG: Well, I mean, it's not objectionable,
18
19
   but it's subject to what we have discussed, because they may
20
    come to some agreements that are narrower than what's written
21
   here.
22
             MR. SLATER: Right, relevant period issues, I think
23
    are what you're bringing up?
24
             MR. GOLDBERG: On this one, we talked specifically
25
    about catalysts and solvents used in the tetrazole ring
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formation process, as opposed to any solvent.
1
 2
             MR. SLATER: That's fine.
 3
             THE COURT: 27? We've got to hear from the
 4
   defendants.
 5
             MR. SLATER: Yeah, sorry, your Honor.
             MR. GOLDBERG: There is no dispute as to this, your
 6
7
   Honor.
8
             THE COURT: 28?
 9
             MR. SLATER: Our understanding is there was no
    dispute.
10
             MR. GOLDBERG: Correct.
11
12
             THE COURT: 29?
13
             MR. SLATER: Same thing, our understanding is there
   was no dispute.
14
15
             MR. GOLDBERG: Correct, your Honor.
16
             THE COURT: Okay. 30?
17
             MR. GOLDBERG: 30, there is no -- is that you?
18
             MR. TRISCHLER: I think so. Unless you want to keep
19
   going, Seth.
20
             MR. GOLDBERG: No, I'm good. Go for it.
             MR. TRISCHLER: Your Honor, under the bioequivalence
21
22
   heading, I don't think there are any issues, except until we
23
    get to 34, which relates to patent litigation. Under the
   heading -- well, if I can explain --
24
25
             THE COURT: No. I mean, I'm going to go right to the
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plaintiff.
1
 2
             MR. TRISCHLER: Okay.
 3
             THE COURT: Come on, what do you want?
             MR. SLATER: It's kind of hard to answer a
 4
   question --
 5
 6
             THE COURT: Well, request denied.
 7
             MR. SLATER: I feel like I'm at my dinner table with
8
   my --
 9
             THE COURT: Objection sustained.
                                               34 is out.
             MR. SLATER: Got it.
10
             THE COURT: Good job, Mr. Trischler.
11
12
             MR. TRISCHLER: You've got to know when to shut up.
13
             MR. SLATER: I feel like I just crumbled on cross.
14
             THE COURT: 35, the testing section. We spent so
   much time on 35 to 44.
15
16
             MR. SLATER: I think we covered it. I think 35 is
17
    covered and 36 is covered.
             And just for your Honor's -- just to note it because
18
19
    it's an issue that may come up in the litigation, 36 focussed
20
    on the first test that they ever -- that they're aware of
   because that's obviously important to us, to set that time,
21
22
    and we think we know when that was. We want to make sure that
23
    that's documented. That's why we pulled that out.
24
             THE COURT: All right. 37?
25
             MR. GOLDBERG: There is no -- none.
```

```
THE COURT: 38?
 1
 2
             MR. SLATER: Withdrawn.
 3
             THE COURT: Great.
             39?
 4
 5
             MR. GOLDBERG: No objection.
             THE COURT: 40?
 6
 7
             MR. GOLDBERG: There is no objection through 43.
 8
             THE COURT: Great.
 9
             44?
             MR. SLATER: I think that's encompassed by our -- by
10
11
    the rulings you've made. Correct?
12
             MR. GOLDBERG: Yes, your Honor.
13
             THE COURT: 45?
             MR. GOLDBERG: No objection, 45 through 51, I
14
15
    believe.
16
             THE COURT: All right.
                                     52?
17
             MR. TRISCHLER: Apparently, this is my turn, your
18
           Can I just turn it over to the plaintiffs?
19
    seemed to work the last time.
             MR. SLATER: Don't go to the well too many times.
20
             MR. TRISCHLER: I think 52, as revised -- I think
21
22
    most of our objections to this section dealt with scope as far
23
    as foreign regulatory matters, and a lot of it was covered by
    the macro discovery rulings. So I think for 52, I don't think
24
25
    there is any objection. And if any of my colleagues disagree,
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or I say anything -- state our position incorrectly, please
 1
   let me know.
 3
             THE COURT: 53?
 4
             MR. TRISCHLER: Subject to -- I would propose for 53
    that it be -- it have the same -- I don't know if the Court is
 5
    looking at the same amended list that I am, but it have the
 7
    same language as 52, as limited by the Court's order. I don't
 8
    think there is any objection.
 9
             MR. SLATER: Does it say "as limited by the Court's
10
    order"?
             Oh, yeah --
             MR. TRISCHLER: On 52, it does, but not on 53.
11
12
             MR. SLATER: Your concern is just about the foreign
13
    regulatory?
             MR. TRISCHLER: Just to make sure it's consistent
14
15
    with -- because, as I understand it, the Court is going to
    enter an order that we have to produce without objection, so I
16
17
   want to make sure that --
18
             MR. SLATER: And I can represent to the Court that if
19
    something is missed like that, we understand that every one of
20
    these requests is as the Court has instructed, unless there is
21
    an exception that we've worked out today or that we work out
22
    later. So I'll be happy to put that in, but we're not going
23
    to later say, oh, that wasn't there, so give us everything --
24
             MR. TRISCHLER: I appreciate that.
25
             MR. SLATER: -- that was limited.
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THE COURT: 54?
 1
 2
             MR. TRISCHLER: Same issue there, your Honor. Again,
 3
    if -- I think, as per -- and it probably applies to almost all
    of these, if we had -- if we amended the language to say as
   per the Court's macro discovery order, I think we would be --
 5
    the defense would be fine with the rest of these.
 7
             THE COURT: Instead of putting it in every request,
 8
   wouldn't it be wise in the general order that is going to be
 9
   entered requiring that these be responded to by X, just say
    that all responses are subject to the macro discovery rulings,
10
    except as otherwise stated from the transcript of December
11
12
   11th?
13
            MR. TRISCHLER: I think that would be fine, your
14
   Honor.
15
             THE COURT: Okay. I will put that in the order.
16
             MR. SLATER: Understood. And, again, we agree with
17
    that.
          We're not disputing that.
             THE COURT: 55?
18
19
             MR. TRISCHLER: No objection, your Honor.
20
             THE COURT: 56?
21
             MR. TRISCHLER: No objection. I think that's been
22
    covered by the macro order.
23
             THE COURT: Can we go 57 to 64? Are there any
24
    objections?
25
            MR. TRISCHLER: That's what I was looking for.
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MR. SLATER: None from the plaintiffs, your Honor.
 1
 2
             THE COURT: Yes, this is --
 3
             MR. TRISCHLER: I don't think so, your Honor.
                                                            Ι
    think we're fine up to 65.
 4
 5
             THE COURT: Yes, noncontroversial area.
 6
             Okay. 65?
 7
             MR. SLATER: I don't think there is a dispute as to
 8
    that.
 9
             MR. TRISCHLER: Yeah, I -- yes, I'm sorry.
    confused because the numbers have 64 and 65. There is no
10
    dispute as to 65, either, your Honor.
11
12
             THE COURT: 66 is out, draft recall notices.
13
             67?
             MR. SLATER: One second, your Honor. 66, should it
14
15
    just be limited to implementation as opposed to consideration?
16
             THE COURT: I'm sorry?
17
             MR. SLATER: I think you skipped 66. You went to 67,
    I think.
18
19
             THE COURT: Okay. Yes, the numbering may be off. I
20
   want to strike the request to produce draft recall notices.
21
             MR. SLATER: Can I indulge --
22
             THE COURT: You could indulge me.
23
             MR. SLATER: Or indulge myself, I quess.
24
             THE COURT:
                        Indulge yourself.
25
            MR. SLATER: And I am going to use Benicar as an
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That case, it became very, very critical when the
 1
    example.
 2
    time came to do a label change -- I'm analogizing,
 3
    obviously -- to do a label change when the FDA said you need
 4
    to change your label, Daiichi prepared a label, and then they
 5
   were ready to submit it to the FDA, but they got a label from
    the FDA that was a weaker warning, and then if you remember,
 7
    the custodian you gave us late in the day overruled them at
 8
   midnight and said don't send ours in because the FDA's is
 9
   better.
             So I would analogize that to this. If they drafted a
10
    recall notice that had certain information that would be a
11
   potential admission where someone wrote and said this happened
12
13
   because of this or something else happened, that didn't find
    its way into correspondence with the FDA or didn't find
14
    itself -- its way into an actual recall notice that was
15
    issued, that could be very probative.
16
17
             THE COURT: Request denied.
             MR. SLATER: Thank you for your indulgence.
18
             THE COURT: Could have, should have, would have -- if
19
20
    that was the standard for discovery, there would be no limits.
21
             So, obviously, final recall notices have to be
22
    produced. I mean, that's easy.
23
             So I think we're up to what, 68?
24
             MR. SLATER: 68 should be okay, right?
25
             MS. HEINZ: Your Honor, this is Jessica Heinz for the
```

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defendants.
 1
 2
             We don't think -- in light of the Court's ruling on
 3
    the macro discovery issues, we don't think there are any
 4
    outstanding issues as to the rest of the requests in that
 5
    section, which is -- I think it goes to 78.
             THE COURT: 68 to 77?
 6
 7
             MS. HEINZ: Yes.
 8
             THE COURT: Can you do the rest of the requests?
 9
             MR. SLATER: Did we -- this might be against my own
    interests, your Honor, but I think on 66, I just want to make
10
    sure that you ruled that it's got to be just implementation of
11
    a recall as opposed to consideration?
12
13
             THE COURT: Implementation.
14
             MR. SLATER: Okay.
15
             THE COURT: Okay. 78? Labeling shouldn't be an
16
   issue.
17
             MS. HEINZ: I think there were two in here that we
    had an issue with. It was the two requests directed -- or
18
19
    seeking documents regarding investors. I think counsel for
20
    Teva wanted to speak about that.
             THE COURT: Oh, the investor statements?
21
22
             MS. HEINZ: Yeah.
23
             THE COURT: Objection sustained.
24
             MR. SLATER: So this is -- which number are we up to?
             MS. HEINZ: I can't recall which number this is.
25
```

```
MR. SLATER: Is it 85? So 85 is out? Is that the
1
 2
    one you're talking about, Jessica?
 3
             MR. RUBENSTEIN: Yes, it's 85.
 4
             MS. HEINZ: I thought there were two --
 5
             MR. RUBENSTEIN: I think they already withdrew one of
 6
    them.
 7
             MS. HEINZ: Oh, okay. All right.
 8
             As to the others --
 9
             MR. SLATER: Wait, what just happened? Is 85 in or
   out?
10
             MR. RUBENSTEIN: Out.
11
12
             MR. SLATER: Okay. I just want to make sure I knew.
13
   Because I just want to make sure that 85 is the one you were
   talking about.
14
15
             MS. HEINZ: (Nods head.)
16
            MR. RUBENSTEIN: Yes.
17
             MR. SLATER: Thank you.
             MS. HEINZ: So I think the request in that section
18
19
   goes from 79 to 92. That was the only one, you know, that we
   had an outstanding issue with. We think the Court's rulings
20
    on the macro issues resolved all the other issues we had on
21
22
    that section.
23
             THE COURT: Can you come up front? I'm only kidding.
24
    I'm not serious.
25
             But, oh, we're through 92? Oh, that's great.
```

```
Because I thought sale and distribution would -- oh, sales and
1
 2
   pricing, that's the difficult area.
 3
             So we're up to 93.
             MR. TRISCHLER: And --
 4
 5
             MS. HEINZ: Okay. So for sales and distribution,
    that went from 93 to --
 6
 7
             THE COURT: I think our numbering is off.
 8
             MS. HEINZ: -- 98?
             THE COURT: The version I have is a little off so
 9
    that's why we might be a little different.
10
             MR. SLATER: Are you looking at the red line, your
11
12
   Honor?
13
             THE COURT: Yes.
14
             MR. SLATER: Sometimes the numbering can be
    confusing. It's the sale and distribution section.
15
16
             THE COURT: Okay. 93 in the sale and distribution
    section, is that at issue?
17
             MS. HEINZ: I don't think -- in light of the rulings
18
   on the macro issues -- I feel like I sound like a broken
19
20
   record here -- but I don't think we have any issue as to 93 to
21
    95.
22
             96 and 98 --
             THE COURT: We may be working from different
23
24
   versions. What number does sale and distribution stop on
25
   yours?
```

```
diligence on what's being purchased. Right?
 1
 2
             MS. HEINZ: We just think that term sounds a
 3
    little --
 4
             THE COURT: Leave it in.
             MS. HEINZ: And then -- I think that was it in that
 5
    section. We think the Court's rulings on the macro issues
 6
 7
   resolved all the other issues through numbers -- the rest of
 8
    that section.
 9
             THE COURT: Okay. Does that take us to
    identification of purchasers?
10
             MS. HEINZ: Yes.
11
12
             THE COURT: All right. So mine starts at 94. I'm
13
    not sure what number yours starts at. But are there any
    issues with regard to this section?
14
15
             MR. TRISCHLER: Yes, your Honor. And the
    identification of purchaser section, there is two paragraphs.
16
17
    The old numbering was 94, which I think your Honor is looking
    at.
18
             THE COURT: That's what I have.
19
             MR. TRISCHLER: The new number is 99. The old number
20
21
    for the second paragraph, obviously, is 95, and the new
22
   numbering is 100.
23
             THE COURT: Okay.
24
             MR. TRISCHLER: The issue that I wanted to raise in
25
   this section is with respect to the second paragraph of that
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section, Number 100. It's overly broad. If you read it in
 1
 2
    context, the plaintiffs are asking for communications between
 3
    and among you, and it starts off with named plaintiffs, which
    is obviously fine, but then it proceeds to expand to basically
 5
    all consumers.
             MR. SLATER: No, just plaintiff consumers.
 6
 7
   plaintiff, including consumers or TPP entities.
 8
             MR. TRISCHLER: Well, but it doesn't identify the TPP
 9
    entities. That's the discussion.
             MR. SLATER: No, it does, right after that. MSP and
10
   Maine Auto Dealers. It says any named plaintiff. This is a
11
    class request, just if there was any communications with the
12
13
   named classes --
             THE COURT: That's what I was going to say. It's not
14
    200-some odd people who filed individual complaints.
15
    just the named class representatives in the three master
16
17
    complaints.
             MR. TRISCHLER: That's -- with that limitation,
18
19
    that's fine, your Honor.
20
             THE COURT: All right.
21
             MR. TRISCHLER: I was going to move on to the sales
22
    and pricing.
23
             THE COURT: Okay. This is -- I hope I'm wrong, but
24
    it seems to me that this is the most problematic area of all
25
    that we're dealing with. So let's roll up our sleeves and get
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it done.

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MR. TRISCHLER: Well, I think, you know, it potentially may be, your Honor, but I think there has been some dialogue that's taken place since your Honor's e-mail of Saturday. We had the meet and confer conference on Monday in which the plaintiffs provided us with some ideas as to what they thought they really needed to get started with the discovery in this particular area. We met collectively as a group on Monday afternoon and again yesterday, and this morning, just very briefly. And, in fairness to the plaintiffs, I'm sure they did not even have a chance to relay what I talked to them about to the entire plaintiffs' executive group, but we talked about proposals and ideas to streamline this issue and hopefully resolve a good bit of it. And, essentially, what we had talked about, and I'll just put it on the record so that there is no misunderstanding, if I may, is that, obviously, we, as a

just put it on the record so that there is no misunderstanding, if I may, is that, obviously, we, as a defense group, believe that the discovery sought on the sales and pricing issue is irrelevant, overly burdensome, and not proportional. But, setting aside all those objections for the time being, we tried to talk about, you know, where might it be relevant, and it seems to have some arguable relevance from the plaintiffs' perspective on the issue of class certification and damage modeling in the class cases.

And so, to sort of get started on this process, what

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the plaintiffs indicated to us that they were looking for, that would be helpful to them and necessary for them to proceed with the case, would be information relating -sufficient to identify customers to whom API and finished dose products were sold; any unique identifiers for those customers, whether it be lot numbers, batch numbers, NDC numbers, whatever unique identifiers that might help track where a product went; quantities sold and when those quantities were sold; and pricing, to the extent -- and to the extent applicable to each defendant, that might be gross pricing and net pricing. On the API side, for instance, we talked about you're probably not getting into net pricing. There is just a charge to the finished dose manufacturer for the valsartan API, so you're probably not going to get into net pricing information. But lower down the chain, you might get into gross pricing and net pricing information. And so, as a concept, we thought about that, and on

And so, as a concept, we thought about that, and on the defense side, agreed to present to plaintiffs and suggest to plaintiffs that what we could provide them -- and recognizing that it might be different among the various defendants, because there is a lot of different entities in this case. Not everyone's data management system is the same. Not everyone's business practices are precisely the same. So how the data ends up being presented to the plaintiff might

differ as between ZHP and Teva and Mylan or any of the other defendants. But what we proposed to them is that, as a compromise on all of these issues and requests, that we would be willing to provide documentation sufficient to identify who our customers are, both on the API and finished dose side; any unique identifiers that are used to -- for those customers, to help plaintiff track product from the finished dose manufacturer to the end user. I don't know if they will be able to complete that chain, but if we have identifiers and information to help with that, we'll provide it. Information regarding quantities sold and when to those customers; and, if applicable, net pricing and gross prices charged for the API and the finished dose.

And when we made the offer, we did so -- I'll state it on the record, the same thing I told the plaintiffs this morning -- that we would agree that that discovery that we would provide would be without prejudice to the plaintiffs' right to come back to each defendant, and there may be questions about the data, there may be additional information that we need to get to the class certification stage, and their expert needs to -- more information, we're certainly open to discussing it.

But, at this particular stage of the litigation, recognizing, as I mentioned at the outset, the concerns that we have with relevancy and proportionality and burden, it

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seems to me that this is a fair compromise that I believe is
 1
 2
   workable -- as always, the devil is in the detail. But for a
 3
    starting point, your Honor, we thought that that was a
    solution to break the log jam, to allow us to get started with
 4
    the discovery. The liability issues obviously are paramount
 5
    in the majority of these cases, both personal injury and the
 7
   economic loss. No reason to hold that up. Let's get this
 8
   preliminary damage discovery started. If there is more that
 9
   needs to be done, it can then be pursued on a
    defendant-by-defendant basis.
10
             MS. WHITELEY: Your Honor, I believe this represents
11
    our conversations. And I quess one question we had for
12
13
   Mr. Trischler which he was able to answer, but due to the
    timing, we couldn't meet with the other defense counsel or
14
15
    bring them into our conversation. He represented that they
    could probably get this information to us within about 60
16
17
    days, which, given the holidays and everything, we thought
    that would work for us and we would be able to work with our
18
19
    experts and be responsive to him.
             If there's a substantial difference in timing among
20
    the other defendants, I think we would have an issue with that
21
22
   because we do see this as a two-part process, at least.
             THE COURT: Mr. Goldberg?
23
24
             MR. GOLDBERG: Your Honor, I would just say for ZHP,
25
    there is -- there is a holiday coming up in China. It's a
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very significant holiday. It's in February. I think if we could have 90 days to do this, if your Honor is inclined to set a time period.
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THE COURT: We'll work with it. I think what you're proposing is very reasonable. I've said it before. I think this pricing information is relevant. It's not only relevant to the liability issues on the economic loss claim, the third-party payer claim, given the Third Circuit's decision, I think it's also clearly relevant to class certification issues, ascertainability, superiority, et cetera.

I think what you're proposing is reasonable, and I'm definitely willing to bless it. I would like it documented, though. Maybe you could take request 96 to -- whatever it is -- whatever numbers they are, and take what Mr. Trischler listed the defendants agreed to produce and list it as a document request.

It's unquestionably clear this is without prejudice to request more. This is a very sticky issue, I think, but it's important to liability, class certification, and also if there ever reaches a point in this case where there is going to be settlement discussions, this type of economic information is clearly going to be relevant.

So the bottom line is, I think what you're proposing is eminently reasonable. Let's give the defendants 90 days because there is a lot of work to do to produce the ESI. This

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is one of the most important issues in the case, so we'll stay
 1
 2
    on top of it, and it will be blessed by the Court. And I
 3
    commend you for working this temporary solution out. That's a
 4
    very reasonable proposal, and it's a way to move forward in
 5
    the case.
             MS. WHITELEY: Your Honor, there is one other thing I
 6
 7
    can add. When we talked earlier, we also mentioned the issue
    of rebates and any other offsets, and I believe what we're
 9
    going to do is try to work through that. It may also be a
    two-part stage, but we're going to try to see if -- discover
10
    as much as we can through conversation and then production as
11
    to that aspect, but I don't think the defendants are familiar
12
13
    enough with the data themselves to even answer those
    questions, so it's going to be a work in progress. Is that
14
15
    your understanding, Mr. Trischler?
16
             MR. TRISCHLER: Yes, I think that's a fair statement,
17
   your Honor.
             THE COURT: No problem.
18
             Sales and pricing, testing, if they're not the most
19
    critical areas in the case, they're amongst the critical
20
    areas. So everything that's been discussed, like I said, is
21
22
    eminently reasonable, and I just want to document it in an
23
    order, and we'll go forward.
24
             So the next area is available data sources.
25
    issues?
```

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1
             MR. RUBENSTEIN: No, your Honor, subject to what the
 2
    defendants keep in the ordinary course of business.
             THE COURT: Of course.
 3
             And then defendants' specific requests, I think those
 4
 5
   have all been worked out, right?
             MR. RUBENSTEIN: (Nods head.)
 6
 7
             MR. SLATER: It's our understanding there is no
 8
    objection to those, your Honor.
 9
             THE COURT: Okay. So --
             MR. TRISCHLER: Well, as to -- well, the first one is
10
           I think Number 115, the Court just ruled on that
11
   Mylan.
    today, Adam. That's the unapproved ANDA. So 115 is out.
12
13
             MR. SLATER: Oh, right.
14
             MR. TRISCHLER: But otherwise -- otherwise, there is
15
   no objection to the balance of those.
16
             THE COURT: Okay. So let's task plaintiff, you're
    going to redraft these, obviously send them to defendants. It
17
    looks like we're going to get together on December 18. At the
18
    end of this session, we'll see if we -- I would love to do it
19
20
   by phone, save you a trip -- but let's get a version to me
   before December 18. If there is any objections, we'll resolve
21
22
    it by phone or in person, December 18. I would like to enter
    an order before the end of the year, just like I said, these
23
   have to be answered without objections, without prejudice to
24
25
   ask for more, or to move to quash less.
```

```
Defendants, 90 days, starting from January 1?
 1
 2
             MR. GOLDBERG: Your Honor, there is just one issue,
    and I should have mentioned it.
             I don't think this kind of information would fall
 4
   within this, but there is a -- there is an additional
 5
   production requirement that we have under Chinese law --
 7
             THE COURT: Right.
 8
             MR. GOLDBERG: -- which is this State secret review
 9
   process.
             THE COURT: What does that mean? Does it mean a lot
10
   of billable hours for people --
11
12
             MR. GOLDBERG: For some law firm in China.
13
             But it does mean that lawyers in China have to get
    involved. They have to help us determine -- and I don't -- my
14
    understanding is there is going to be some categories of
15
    documents that fall within State secrets.
16
17
             THE COURT: Can you send me a letter, what you want
18
    after you get your arms around this?
19
             MR. GOLDBERG: We'll try to figure that out.
20
             THE COURT: I'll say 90 days, but I understand you
21
   might have a problem. If there is good cause, you'll get more
22
    time.
23
             MR. GOLDBERG: Thank you, your Honor.
24
             MR. TRISCHLER: Your Honor, you made a statement
25
    about 90 days, and I apologize, I was not sure what you meant
```

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by that.
1
 2
             THE COURT: To produce the responsive documents and
 3
   ESI.
             MR. TRISCHLER: For?
 4
 5
             THE COURT: The document requests.
 6
             MR. GOLDBERG: I'm sorry. I thought you were talking
 7
    about the sales and pricing information.
 8
             THE COURT: No, no. Well, I gave you 90 days for the
 9
   sales and pricing. You got that.
10
             How much time do you need to -- they should already
   be working on this.
11
12
             MR. GOLDBERG: Your Honor, this set of requests,
13
    coupled with the number of custodians and the number of search
14
   terms --
15
             THE COURT: So what are you collectively -- what are
   you thinking?
16
17
             MR. GOLDBERG: I think we should revisit it, the
    timing, after we resolve some of the other issues.
18
19
             THE COURT: Okay. All right. You know what we can
20
    do? It's going to be a rolling production, so there's
    certainly going to be responsive documents --
21
22
             MR. GOLDBERG: Sure.
23
             THE COURT: -- that are easier to get than others.
24
   But you're right, let's wait until after custodians and search
25
   terms.
```

```
So it's 11:47. Why don't we take a ten-minute break,
 1
 2
    and then we'll go to custodians, and then we'll do search
 3
    terms. Okay?
             THE DEPUTY CLERK: All rise.
 4
 5
             (A recess was taken at 11:48 a.m.)
             THE DEPUTY CLERK: All rise.
 6
 7
             THE COURT: Please be seated.
 8
             (Pause)
             THE COURT: I read your papers on the custodian
 9
           Is there any real dispute other than the number of
10
   custodians for ZHP?
11
             MR. SLATER: Well, there is a dispute as to whether
12
13
    or not we should be driven by a mathematical number or whether
   we should be driven by what we need. And you understand our
14
15
    different approach to this --
16
             THE COURT: No, I --
17
             MR. SLATER: -- but if we just look at the numbers --
18
             THE COURT: Is that the only dispute left with regard
19
    to custodians for ZHP?
20
             MR. SLATER: Yeah, I would define it as substance
21
   versus a naked number. We are actually arguing --
22
             THE COURT: Put ZHP aside. Are there any other
23
   disputes?
24
             MR. SLATER: No. Oh, I'm sorry.
25
   misunderstanding, Judge.
```

```
THE COURT: That's what I meant.
 1
 2
             MR. SLATER: They're like -- listen, okay, yes.
 3
    There is no other issue. Sorry.
             THE COURT: You can translate for me then.
 4
             MR. SLATER: Apologize.
 5
             THE COURT: Okay. We're discussing ZHP and the issue
 6
 7
    is, I think, ZHP says I want a limit of 50 custodians, and I
 8
    think the plaintiffs say you want 123.
 9
             MR. SLATER: We're at 139, between all of the ZHP
    entities, so they're not all just ZHP. The ZHP total is 107,
10
    and then there is Solco, Princeton, and the other
11
12
    subsidiaries.
13
             THE COURT: So how do we resolve this?
             MR. SLATER: Oh, it's very easy. We have presented
14
15
    you a spread sheet. We have provided justification for
    anybody that is either disputed or as to which we have no
16
17
    response, which I believe provides a prima facie good-faith
   basis to include them as custodians.
18
             Your Honor should know that there have been many
19
20
    other people that have been on this list through the meet and
    confer process who we have deleted based on what we believe to
21
22
   be good-faith representations as to people either not having
23
    involvement with valsartan or not being necessary, and we
24
   have -- so the list is not what it originally was, and there
25
    is a lot of names that are off or were not added. But this is
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what we believe to be a narrowly tailored list to the
 1
 2
    information we have available, and the -- you know, we gave
 3
   you numbers in Benicar. We're not even close to those
   numbers.
 5
             I mean, in Benicar, we got 115 custodians from
    Daiichi U.S. and 68 from Japan, so that's a far higher number
 6
 7
    from that one entity, and then Forest was 47 custodians, so if
    you analogize, if we're just going to talk the numbers to
 9
    start with their argument, we're far less than that, and in
    what they have already told you multiple times is a far more
10
    complicated case. And, again, we provided justification for
11
    each person. We're not just asking for these people in a
12
   vacuum.
13
             THE COURT: Was this list attached to the letter --
14
    the December 10 letter?
15
16
             MR. SLATER: I believe so. It should have been.
                                                                The
    spreadsheet should have been submitted. And you know what?
17
18
    have an extra copy.
19
             THE COURT: Okay.
20
             MR. SLATER: I brought one for your Honor. This is
21
    exactly what I'm looking at.
22
             THE COURT: Yes, let me take that.
23
             MR. SLATER: It's not actually not in the tiny type.
    It's actually a little larger.
24
25
             THE COURT: Oh, good.
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MR. SLATER: Is it okay if I approach?
 1
 2
             THE COURT: Please.
 3
             MR. SLATER: (Complies.)
 4
             THE COURT: So Mr. Du is going to be on the list.
    That's -- that's not an issue. He's on the list. So let's
 5
   not talk about Mr. Du.
 7
             MR. GOLDBERG: Your Honor, if you're inclined to go
8
   down a list, then I'd like to hand something up.
 9
             THE COURT: Sure.
             MR. SLATER: Is this something we have?
10
             MR. GOLDBERG: This is your list that you provided
11
    yesterday, and we have a second column that provides the
12
13
    objections that we've had that we've stated over and over and
    over again, and would be happy to have your Honor review
14
15
    those.
16
             THE COURT: "NA" is?
17
             MR. GOLDBERG: "NA" -- and, your Honor, what "NA" is,
    so the first --
18
19
             THE COURT: No objection?
20
             MR. GOLDBERG: -- 42 are --
21
             THE COURT: Oh, that's great.
22
             MR. GOLDBERG: -- the agreed upon.
23
             And while your Honor is looking at that, let me
24
   provide your Honor with -- what -- those 42 agreements, those
25
   are the ZHP-proposed custodians, and this is the
```

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1
   description --
 2
             MR. SLATER: Could I ask a question? Where is this
 3
    coming from? We've never seen this before, right?
 4
             MR. GOLDBERG: Yeah, you have seen it in every letter
 5
    that we've provided to you, and we have covered it in every
   meet and confer.
 6
 7
             THE COURT: Talk to the Court, talk to the Court.
 8
             MR. SLATER: I have a real problem, your Honor, with
 9
    them doing now what they should have done in the briefing to
    the Court so we could have responded to it.
10
             And the issue is this: We've laid out
11
    witness-by-witness descriptions of why they were necessary,
12
13
    including where we couldn't get substantive information.
    did everything we needed to do to brief this. And, now, as I
14
    was concerned it might happen, and, unfortunately, it's
15
    happened now, counsel walks in and they want the Court to say,
16
17
    well, okay, let me look at these substantive objections now
    that were not documented in the papers witness by witness. I
18
    think that it's really -- you know, it's not a good practice
19
20
    and it's a bit of a sandbag.
21
             But I think if we go with the papers that were filed
22
    with the Court before we walked in today, we have provided for
    the Court substantive justification for each person that's
23
24
            The number is very manageable. It's far less than
    needed.
```

what was ordered in the Benicar case from a defendant with a

25

much more straightforward and simpler case. And throughout this process, we did not get the type of information that would be needed, for example, to say, well, these are duplicative. And we cited the case that showed the cases they had cited did not apply, because in that case, and that was the Ramirez case, the Court said, well, when you look at these other cases, for example, Enslin, the defense actually did custodial searchs before they came in and proved that documents were duplicative. That hasn't been done. In fact, they have told us they have never collected documents for custodians, they've never run sample tests, they've never done anything.

So we've made a good-faith showing as to these, and on the record before the Court, before they walked in with whatever this stuff is, which I don't have time to read and learn right now because I've never seen it, we've made a good-faith showing and they have not.

Their entire argument was you only need 50 people. So I believe that's the issue that was set up for the Court in the briefing. Did we make a good-faith showing as to the people we're asking for, and, if so, should that trump a arbitrary, hey, just take 50 -- which I don't even know where they come up with that number, because they've looked at Benicar, the number was far higher, for a less complicated case.

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THE COURT: Mr. Goldberg, on your chart, the column
 1
 2
    "Plaintiffs' basis for inclusion," is that taken verbatim from
 3
   plaintiffs' chart where it says "explanation"?
 4
             MR. GOLDBERG: Yes, your Honor.
 5
             THE COURT: Then what is this?
                           Okay. So, your Honor, what you have,
 6
             MR. GOLDBERG:
 7
    first of all -- and to call this sandbagging is really --
 8
             THE COURT: Let's get to the merits.
 9
             MR. GOLDBERG: Okay. The defendants' objections,
    okay, so if you look at Number 43 on this spreadsheet I gave
10
    you, this is where we start with their proposed additions as
11
    of yesterday. And this is information -- name, the title, et
12
13
    cetera.
             Defendants' objections, we pulled this from the
14
    letters that we provided to you or that we gave to them and we
15
    attached to our brief. So on November 14th we sent a letter,
16
17
   November 22nd. All of this information is in those letters.
    We've identified to them how -- for instance, Number 43 is
18
    duplicative and cumulative of Number 10, Number 11, and Number
19
    12. That's in our letters. We've told them about
20
21
    high-ranking officials. We've told them, if you go down,
22
    you'll see, we're just pulling from our letters to them the
   basis of each objection as to the witnesses.
23
24
             Now, it isn't correct that we're asking for a limit
25
   of 50. We proposed 42 custodians. That's what this document
```

```
These are the 42. They cover every department at ZHP
 1
 2
    that matters. They cover Prinbury, Solco, Princeton, all of
 3
    the related entities. They cover manufacturing, testing,
    quality control, quality assurance, regulatory, sales.
    They're -- have been identified by our client through numerous
 5
    conversations as the people with the most important,
 7
   meaningful -- meaningful involvement with valsartan in all of
 8
    these areas.
                 These 42 were in the subject of the interview
 9
    with Mr. Du.
                 He confirmed them. It's important to note, your
   Honor --
10
11
             THE COURT: Is Mr. Du on your 42 list?
12
             MR. GOLDBERG: Mr. Du is not -- well, Mr. Du -- we're
13
    not opposed to Mr. Du --
14
             THE COURT: He is 43.
15
             MR. GOLDBERG: We're not opposed to him being
    included. Our job was to identify the people meaningfully
16
17
    involved with valsartan in these areas. We're not opposed, if
    they want -- if they want to include him. And that's why we
18
19
    suggested, if they want to go up to 50, and they have eight
20
    other or seven other people they want to choose, that's their
            Okay? But the law says, the standard is, that the
21
    choice.
22
   parties try to identify the people that are most involved.
    And if you go back to their October 3rd letter, that's what
23
24
    they were asking for -- primary responsibility, most
25
    knowledgeable. That's exactly the words in their letter.
                                                               And
```

that's what we did. That's these people.

Importantly, your Honor, you ordered Mr. Du to be here. They went through all of the org charts. They asked him about these people. They only asked him about six of the people on the -- that remained from 43 to 140. They only asked about six of those people. All of these people have been identified either in core discovery or on the website or on LinkedIn. And what we have done is identify -- and you can read each of the descriptions of these people. And they're undisputed, there is no dispute that these people are the material people. And what we suggest is that -- and mind you, these 42 would be more than any other defendant. Some of the defendants are up to 25. We've gone from 7 to 42. If you go to 50, we're probably double every defendant.

The point about Benicar is a little bit of a trap because if your Honor wants to go there, Benicar -- your Honor may not recall, but there was a decision your Honor wrote -- there were 64 million pages of documents produced in Benicar. I don't know if the Court wants to encourage that kind of volume here on a case that has a specific manufacturing issue, especially where the 42 people we've identified will provide all of the material information. The people that they've identified on this list are ancillary. There is no question that they're going to have some information about valsartan. That's not the standard, though. The standard is is it going

to be duplicative?

If I show you an org chart and I can say, okay, the people they listed, the people above them are on our list — they can show you documents where there are seven people listed. We've identified four of them and they want three more.

There is a report, it has 18 people attended a close-out report for the FDA. We identified 10. They want the other eight. That kind of duplication, that kind of cumulativeness isn't warranted at this stage, especially considering that when you're talking about the burden of translating Chinese documents, the cost of a dollar per page for some of these documents to be translated, the time of State secret review — the magnitude of 64 million pages, we set this forth in our brief — it would take five years, a hundred lawyers five years to review that.

THE COURT: Mr. Slater, is there any reason I can't look at this document that Mr. Goldberg has given us, which incorporates your comments, and decide whether it's appropriate for each of the individuals to be included? I'll have your position, I'll have their position, and I can make the call myself.

MR. SLATER: Well, I mean, I would have liked to have had that in advance, so that all of us that were involved, including, for example, my associate, Chris Geddis, who

conducted the meet and confer yesterday on the most recent org chart, could have actually looked at what they were saying here to say, well, there's not right or this is what happened. It would have been nice if we actually had that on the schedule that we should have had, so we could know what they were actually going to say to the Court. That would have been helpful.

I'll tell you a few other things.

What they're basically saying to you is we concede that everybody the plaintiffs have listed had involvement with valsartan at some level. So we don't have somebody that's on the outside. When they said something had no involvement, we took them off the list, and we said if later the person's name pops up on a relevant document, we'll talk to you then. We took that at face value. So this is a narrow list that they are not saying that we have irrelevant people.

Let's use Jun Du as the bellwether to this. They're still looking to you and saying on their standard, Jun Du is not a necessary custodian. I am happy to take Jun Du as the bellwether to this list because they have cemented their position as the Jun Du example is the process that they followed in analyzing every one of these. And the Court knows and everybody involved in this case knows that if that's the test, the Jun Du test, they fail miserably and we get everybody.

It's clear, they state that at the Jun Du meeting, we didn't ask about somebody. We asked about every single thing we could, every single word on those papers. Counsel said we asked about the org charts. We asked about the org charts that were produced in Chinese the night before, and that then during the meeting, we -- we were being told, well, this name means this, that word means that. And we said, well, who are these people? And the answer to a lot of the question was: You'd have to ask someone else who worked in that department. They could tell you specifically.

For example, there were people who were involved in the testing and evaluation of testing in that department. We know from them they all had involved with valsartan at some level. He said, well, I can't tell you what tests this person did or what tests that person did. Okay? So, and you look at the Ramirez case, and the Ramirez case said if they want to say that people are duplicative, then they need to have run the testing across the documents to show we've proven that there are no duplicative — that all the documents are duplicative. We know that's never been done. So there are all of these gaps in their opposition.

And, again, what we've put in front of your Honor is a narrowed list where they do not dispute that every person on the list was involved with valsartan.

So I frankly don't think your Honor needs to retire

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IN RE:

VALSART 5052 STATUS/DISCOVERY CONFERENCE

from this court, look at these lists, and make decisions person by person because based on the law and based on what's before you on the record, they are not disputing involvement, they're not showing you a lack of involvement, and your Honor has seen the discussions and you know how this is going. can't have gaps on something as important as, for example, the testing or the quality assurance, et cetera.

Counsel just listed you all of the entities that we've named custodians for to the ZHP Group, and the number is only 139. However many documents that is going to elicit, it's going to elicit. The search terms are going to define it, and if they think that certain witnesses are only going to have a small number of documents, so there is no burden -certainly, no appreciable burden, versus what the prejudice to us is if an important document doesn't get captured because, for example, this one custodian saw a test result and wrote in a document or a memo, this is a concerning peak, I talked to such and such and they don't want to test it, and we don't capture that person, it's terrible.

There is another problem. In the meet and confer, we have been told, although we have no specificity on this, that for many people, all their e-mails have been destroyed. We don't have specificity on when or why. It will be helpful when we see the document preservation policies to understand. We don't have an answer of whether they had backup tapes.

when we know that witnesses' e-mails have been destroyed, it's that much more important to have more witnesses because we're losing the ability to capture things. So we need to hope that somebody has an e-mail in their records because if they went and whitewashed the files of a bunch of people, especially people going back in time, my gosh, that's a significant gap in our knowledge base.

So, again, your Honor asked the question, obviously, you know, you can look at what they have now put in front of the Court for the first time at the 13th hour, but the record demonstrates we need all of these custodians because there is no showing we don't.

And I'm reading through what they put into the defendants' objections section. I'm looking at Number 47 on their list, for example, because it just happens to be one I looked at first: Jun Du interview, plaintiffs could have asked about this person. Okay. That can be swept aside. We asked about every person whose name came up, and there came a point where we were told don't bother to ask; the answer is going to be the same, as your Honor knows.

He reports to two people who are listed. That's good. That means that he's in a lineup of people they agree are relevant.

Then, his routine job function: Not a decision maker. Quote, "involved in data review and other lab

management works for valsartan." That sounds pretty important.

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Manages the physical and chemical group of testing raw materials, supervises lab jobs, and reviews related data and documents, does routine physical and chemical tests of raw materials, generates and reviews raw material tests. Doesn't work with residual solvents, not involved in cleaning machinery. Okay. There is enough there, this person is obviously somebody we need.

I flipped through this and, obviously, I'm seeing it for the first time. The refrain is the same. The people with the most meaningful involvement -- your Honor knows well from managing so many cases that -- they started with eight people. Remember where we were in the beginning, your Honor. walked in with eight people and looked you in the eye and said, that's all they need. Those are the only people that matter. The number is climbing as we scratch and claw to get a little more information. But we have never ever proposed somebody to this Court where we couldn't make a showing they were involved. And, again, they're asking you to take it on face value that someone doesn't matter or isn't as important. We have to prove our case. With an admission that e-mails have been scrubbed, with all of the gaps in Jun Du's knowledge? With all of the things they haven't been able to answer? And I'm not doubting that they can't answer the

questions because I think there is a huge gap in communication out of China, and I think it's going to be a continuing problem throughout this litigation. There is going to be a reticence on the part of ZHP to provide information and documents. I think it's going to be an issue we're going to face many times in this litigation. I hope I'm wrong, but I think that's an issue we're going to face, and I don't blame it on the counsel. I think it's going to just be a factor of the type of litigation we're going to have here.

So I don't think -- of course, your Honor can look.

I don't think you need to. I think on the record before this

Court, we have a good-faith list, covering five or six

companies, of a very manageable number of people based on

historical numbers in Benicar and other litigations. We ask

that you order our custodial list to be utilized.

THE COURT: Any last word on this, Mr. Goldberg?

MR. GOLDBERG: Yes, your Honor. I -- it is critical that your Honor think about that Jun Du interview, okay?

Because the vast majority of the people on this list, they plucked from documents in the core discovery. So they walked into that meeting on June -- on October 23rd, and they had the opportunity to ask Mr. Du about all of the people that they could identify in core discovery. The documents that they've used to compile their list, and I'll just hand one up, if you don't mind.

They went through the reports, and there are thousands and thousands of pages of testing and reports, and at the beginning of each report are the people who author the report and then review it, and then it goes up the line to who approves it. And there is no question, I mean, this is a major company. These -- some of these people are line employees. Some of these people are authoring the tests. They're going to get the tests. Your Honor determined that they're going to get all of the tests.

What they did is they've taken multiple names from the same document and said these are good custodians, simply because they had some involvement in valsartan. And that is not the standard. If that was the standard for litigation against corporate clients, any line employee on a conveyor belt or some other space in a factory would be a potential custodian. That can't be the standard, especially given the cost of ESI, especially given the Court's schedule, especially given the narrow issues in this case, and especially given that they're gonna get the actual test reports. In our view, the approach is, it has to be a limit.

And courts set limits all the time. The Federal Rules set limits. They don't say you can take as many depositions as you want. They don't say you can have as many interrogatories as you want. You have to set limits to have some -- to have some efficiency. That's the purpose of this

MDL.

Nothing is prohibiting them. And we've said to them, we proposed to them, if you come back, you look at a test and you say, boy, we really need to ask this person why, when he drafted this test, there is a number, or why did -- why did he -- what did he think when he reviewed it? I mean, the reality is, lower-level people are reviewing tests about all of the 30 products that val- -- that ZHP makes, indiscriminately. And the likelihood that any one of them would remember a specific test that would provide meaningful probative information about whether the test itself shows a peak, that cannot be the standard.

But, more importantly, what Mr. Slater has proposed is wrong. These are line-level employees, lower-level employees. They may not have a lot of pertinent information about valsartan, and so he may say that the burden of having them produce information is low. That's not true. The same search terms are going to be applied to their files. They work for every one of the drugs at ZHP, so their custodial files could be huge. So a term like "FDA" or whatever the terms are being used that pertain to pharmaceuticals are going to apply to their entire custodial file. And the burden is that we're going to have to look through and determine how much of this stuff is not responsive. And that is — that's going to take years. And that's not — and Benicar shows — I

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would ask you, Judge, how many of those 64 million pages did
 1
 2
    the lawyers in Benicar look at?
 3
             MR. SLATER: Every single one of them.
 4
             MR. GOLDBERG: Every single one of them. Okay.
             THE COURT: The question to ask is how many --
 5
                           How many were relevant?
 6
             MR. GOLDBERG:
 7
             THE COURT: -- were reviewed? The right question
 8
    isn't how many they looked at but how many were relevant or
 9
   meaningful to the case.
10
             MR. GOLDBERG: Right. That's the better question,
    and that's the point.
11
12
             There is no basis here to go down that road now.
13
    Whether it's 50, maybe it's 60 -- maybe your Honor wants to
    say take 60, choose another 17, that's -- whatever it is. But
14
    there has to be a limit.
15
16
             THE COURT: Here is what the Court is going to rule.
    I have told you this before and I'll say it again. I'm just
17
18
    not a very good poker player.
             In Benicar, the Court made hundreds, if not
19
    thousands, of decisions. And my friend from Benicar is in the
20
   back. And, of all the decisions the Court made in Benicar,
21
22
    there is only one I regret, and I think that was too many
    custodians were identified in Benicar. And, of all the
23
24
    decisions I made in that case, that's the only one I question.
25
             Here's what the Court is going to do. The standard,
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obviously, is not anyone who touched valsartan is a relevant custodian in the case. We all know that.
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Plaintiff, you get 50. By the end of today, pick your next 25 -- pick your best 25. The rest, it would be 25 plus 39. I'll look at the list, and I'll make the call whether they should be included or not, and that will be the final list for the first tranche of discovery.

I don't see how plaintiffs are prejudiced, in all candor. One, they're going to get a mammoth amount of information; plus, it comes with the proviso that if there is good cause for additional custodians — and we did this in Benicar, we added some, we subtracted some — you'll get it. And if it turns out there was a relevant custodian that we missed, you'll get it. If it turns out one of the custodians that are listed shouldn't be on the list, too many irrelevant hits, we'll take them off. I don't know how to do it other than to set a finite number in the first instance of custodians, so there is going to be a number between 50 and 139. It's going to be at least 75, so it will be somewhere between 75 and 139. And whatever 75 you don't pick, I'll make the call.

So I would suggest you use the numbering on -because your chart is not numbered, use the numbering on
Mr. Goldberg's chart, and if you could get that list to me by
the end of today, I'll get you rulings on the final list of

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custodians by noon tomorrow, so we could put this to bed.
 1
 2
             MR. SLATER: So, if I understand, your Honor, it's --
 3
    I think they said they have agreed to 42, is that the number
 4
    they have agreed to?
 5
             MR. GOLDBERG: Yes, that's the number.
             THE COURT: So take your 42 and then add -- 8 plus
 6
 7
    25 -- 33. That will give you 75.
 8
             MR. SLATER: And then if we want more than 75, that
   will be something for the Court to determine?
 9
             THE COURT: I assume you're going to want more than
10
   75 because there is, presumably, 139 listed on here.
11
12
             MR. SLATER: Yeah, we want 139.
13
             THE COURT: I know you want 139.
14
             MR. SLATER: I'm joking, I'm joking. I get it.
15
             THE COURT: Well, there is 135 on here.
             MR. SLATER: Our total is 139 from all the entities.
16
17
             THE COURT: Then why does this list have 135?
18
             MR. SLATER: I don't know. Maybe when it was
19
    counted on our end -- one of us is wrong.
20
             THE COURT: I'll tell you what. It will be 75 plus 1
   because Mr. Du is a custodian. You don't have to waste one of
21
22
    your draft picks on Mr. Du.
23
             MR. SLATER: Okay.
24
             MR. GOLDBERG: Your Honor, why not just say 75, and
25
   then later in the case, if there's cause to go above, we go
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Because how could there be material information, given
 1
    above?
 2
    our 42, given another 33, that they're not going to get?
 3
             THE COURT: Mr. Goldberg, a year from now, you're
 4
    going to look back on this and you're going to say, thank you,
 5
    Judge Schneider. You know why? Because it's cheaper and more
    efficient for your client to do an overinclusive search one
 7
    time in the short term than for the Court to require your
 8
    client to go back and do two, three, four separate searches.
 9
    So you may not be happy with it now, but in the long term,
    you're going to be happy because I'm saving your client money.
10
             MR. GOLDBERG: I don't disagree. It's already
11
   punitive. It's already going to cost in the many millions of
12
    dollars. That's where the 42 witnesses -- the 42 custodians
13
   were. The jump to 75 is not incremental. It's drastic.
14
    go above 75, that just compounds an already drastic situation.
15
             THE COURT: So now I know the Court is comfortable
16
   with its ruling because Mr. Slater is not happy with me under
17
    his breath, and you're not happy with me under your breath, so
18
19
    that means I hit it right in the midpoint. Okay?
20
             So by the end of today --
             MR. SLATER: I'm more unhappy than he is. I just
21
22
    know how to take it.
23
             THE COURT: By the end of today, get me your list.
24
    You can do it by e-mail, Mr. Slater; obviously, copy
25
   Mr. Goldberg. And by noon tomorrow, you'll get your final
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list.
1
 2
             MR. SLATER: Can I ask -- I just want to place one
 3
    thing on the record and make the Court aware and just make
    sure it's clear so there is no question later. We're still
 5
   getting org charts from ZHP. We're still getting information
    about people. So I just -- I just want it to be clear that
 7
    I'm astounded that defense counsel is upset when they
    stonewalled us and --
             THE COURT: Does this advance the ball? Let's focus
 9
    on the merits.
10
             MR. SLATER: I just want the Court to be aware and I
11
    want the record to show we're still getting the names of
12
13
    custodians today. I understand the good cause standard.
    just wanted to make sure that that was clear because we're
14
15
    still waiting for a lot of information.
16
             THE COURT: Okay. So, with regard -- like I said, I
    wanted to put all of this in an order. I know with regard to
17
    the non-ZHP defendants, you've agreed on a number of
18
19
    custodians, maybe it's 25, but you've only identified 16.
20
    Somehow we're going to have to put that in an order. I would
    prefer that you identify the 25 so we could put it in the
21
22
    order, but I want to wrap this up. I want to tie it with a
23
   bow. I don't want to come back in January and deal with
24
    custodian issues. Today was the day that we were supposed to
   resolve all of these issues.
25
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1
             MR. SLATER: Can I suggest, only because there is a
 2
   bunch of people who are going to need to do that, and I think
    it's exactly what your Honor should do, as we did in Benicar,
   have a list that you attach to the order --
                        That's what I'm going to do. That's what
 5
             THE COURT:
 6
    I plan to do.
 7
             MR. SLATER: The only thing I would ask, and I think
 8
    it would make sense on all these, if we get a couple days,
 9
    only because a lot of people are going to travel now, they're
    going to run out of court and get on planes, and we want to do
10
    it the right way. So if we could have till -- we're not
11
    getting to the 18th -- another day or two, just to get you the
12
13
    list.
14
                        That would be okay.
             THE COURT:
15
             MR. SLATER: I just want to make sure --
             THE COURT: I would love to be in a position by the
16
17
    18th --
             MR. SLATER: Yes.
18
             THE COURT: We'll be done, I'll have the list, I'll
19
20
   have all the terms, the names. I will attach them to an
21
    order, so you can all enjoy your Christmas vacation.
22
             MR. SLATER:
                          Thank you.
23
             So can we also apply that to the extra -- at least
24
    give us another day to get the list to the defense and to the
25
   Court on the ZHP custodians? Only because there is people
```

in re: vals**ragan**: 5064 atus/discovery conference

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that are not here who I would want to have involved in that
 1
 2
    discussion as to who we're selecting. There is people that
 3
    are not here that just are important to that discussion.
 4
             THE COURT: All right. Today is Wednesday, so when
    can I get your list?
 5
 6
             MR. SLATER: I would say by the end of tomorrow.
 7
             THE COURT: Fine.
 8
             MR. SLATER: By 5:00 tomorrow?
 9
             THE COURT: Fine.
10
             MR. SLATER: Thank you.
             MR. GOLDBERG: Your Honor, I may have missed
11
    something. What list are you proposing to get to --
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13
             MR. SLATER: I'm proposing our list of the 76 and
    then anybody we want in addition --
14
15
             THE COURT: No, no, no. It's just -- just give me
    the 76.
            I'm assuming you want everyone on this list. There
16
17
    will be 76 identified, and I'm going to decide whether you get
18
    anyone else.
19
             MR. SLATER: Okay, now I understand. Thank you.
20
             So we'll get the list of 76 to your Honor by 5:00
    tomorrow, and we'll also obviously give it to Mr. Goldberg as
21
22
    well, and then -- now I understand how you're going to handle
23
    it. I didn't understand that before. Thank you. I'm sorry.
             MR. GOLDBERG: Your Honor, just one point. If you're
24
25
    going to be using this thing that I handed up to review, the
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last ten entries were entries that were added by plaintiffs
 1
    last night, so we haven't had a chance to put our objections
    in. Because those ten custodians were only identified --
 4
             THE COURT: Okay. As long as I get it by close of
   business tomorrow.
 5
 6
             MR. GOLDBERG: We'll send this to you with that
 7
    information filled in.
 8
             THE COURT: I would just need those two pages then.
 9
    I don't need the whole reprint.
10
             MR. GOLDBERG: Yes. Okay.
             THE COURT: All right. So, with regard to these
11
    custodian lists then, before next Wednesday, which is the
12
    18th, I will get the final list of custodians for each of the
13
   API and finished dose manufacturer defendants. I'll get the
14
    final version of the requests for documents.
15
16
             Now let's go to the search terms. I read your
   proposal. I think your proposal is eminently reasonable. I
17
    would like to put that in an order. I don't know the exact
18
19
    language you use, but test runs, et cetera, et cetera.
    think it's eminently reasonable. But there was one finite
20
21
    category of disputes, right?
22
             MR. PAREKH: Correct, Your Honor.
23
             THE COURT: All right. Let's deal with the disputes
    regarding the search terms. And could you help me point to
24
25
   where in your letter I'm going to find that?
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MR. PAREKH: It's in our letter on Page 11, Section
 1
 2
   В.
 3
             THE COURT: Got it. Remaining dispute as to
    CGMP terms. And the specific items in dispute are those
 4
 5
    listed on Page 12?
 6
             MR. PAREKH: That's correct, Your Honor.
 7
             THE COURT: There are only seven items in dispute?
 8
            MR. PAREKH: There is seven items, and defendants
    characterize it as 17 terms because some of them are
 9
    essentially the same words but in different formats, so 7 or
10
    17.
11
12
             THE COURT: Is that all we're arguing about?
13
            MR. PAREKH: That's all we have for you. We worked
   very, very, very hard to come up with the rest of this.
14
15
             THE COURT: Defendant, who is going to speak to this?
16
             MR. TRISCHLER: I will be happy to, your Honor.
    don't know that anyone else is jumping out of their seat to do
17
18
    it, so I'll be happy to.
19
             THE COURT: 7/17 additional terms, that's what we're
20
    arguing about?
21
             MR. TRISCHLER: Yes, sir.
22
             THE COURT: We're arguing about whether the term
23
    "whistleblower" should be searched for or "bury" or "coverup"?
             MR. TRISCHLER: Yes.
24
25
             THE COURT: Is that not relevant to the case?
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IN RE: VALSRAGAND: 5067 ATUS/DISCOVERY CONFERENCE

1 MR. TRISCHLER: It's absolutely not relevant, your 2 It has nothing to do with the issue of whether there 3 was an impurity in this medication --4 THE COURT: Agreed. But isn't there enough smoke 5 signals out there that there might be a problem that some of the defendants have not been doing what they're supposed to 7 with their document retention program? Isn't there enough out 8 there on that? MR. TRISCHLER: No. I don't -- frankly, your Honor, 9 there is nothing out there. 10 And what the plaintiffs have pointed to with respect 11 to some of the 483 documents that have been produced in core 12 13 discovery or that the plaintiffs have acquired through FOIA requests are what might be perceived or referred to as 14 irregularities in data collection or data management. 15 are search terms to collect at. We have search terms that 16 17 have been agreed upon regarding data integrity, data reliability. So if those -- if those issues exist, they will 18 19 be captured in the, I think, 483 search terms that the parties 20 have agreed to. You know, to allow the plaintiffs to run amuck on a 21 22 conspiracy theory that, you know, all of these defendants were trying to hide data and information regarding nitrosamines, 23 24 it's preposterous, and, you know, at some point, when we are 25 all producing millions and millions of documents, you've got

```
to draw a line. And --
1
 2
             THE COURT: I agree. But if you look at these terms,
 3
    if it was a generic term -- I'm not a linguist, but if it was
    a generic term that is likely to result in an excessive number
 5
    of hits, you'd have a great point. But is it likely that a
    search for "coverup" or "disaster" or "delete" or "bury" is
 7
    going to come up with -- again, I'm not a linguist, but is it
 8
    likely, applying common sense and what we know, that a search
 9
    using those terms is going to uncover an excessive number of
    documents?
10
11
             MR. TRISCHLER: I would not expect it to, your Honor,
    quite frankly --
12
13
             THE COURT: So what's the harm? What's the harm?
   Actually, it could help you because when they come back -- the
14
   plaintiffs come back undoubtedly and say, we want to do a
15
    search in the future using more search terms, you'll say,
16
17
    Judge, we were here on December 11th and you gave them
    everything they wanted, right?
18
             MR. TRISCHLER: The harm is the suggestion that the
19
20
    defendants have engaged in a scheme to cover up or obfuscate
    the truth with respect to nitrosamines in ARB medication. It
21
    didn't happen. There is no validity to the suggestion. In
22
    fact, if anyone's paid attention to anything that's gone on in
23
24
    the health community for the last two years, what regulatory
25
    agencies around the world are starting to find out is that no
```

one appreciated, rightly or wrongly, the potential for nitrosamine, trace amounts of nitrosamine impurities, to find their way into medications. That's why you're seeing recalls of other products that have nothing to do with ARBs. This wasn't some coverup.

And I guess my objection to it, and on behalf of the defendants, our objection to it is that we're going to chase our tail on this wild theory that there was an attempt to cover up data, when we've got more important things to do and we've got bigger fish to try, and our attention should be focussed on the liability issues and not a book that some woman wrote that took potshots at the defendants, which are some of the search terms that are in there. It has nothing to do with the issues in this case.

THE COURT: But I recall seeing documents in this case, FDA documents, which talked about -- these are my words, not the FDA's documents -- that there were questions raised about the -- destruction may not be a right word, but discarding of documents, and I recall seeing documents in this case about -- you know what I'm talking about. You've seen those documents. So if this was an entirely speculative venture, yeah, you have a point. But there is a record in this case that there is good cause for the plaintiffs to at least inquire into this subject matter. They're not pulling this out of whole cloth. They're relying on FDA documents.

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So my ruling is that the defendants' objections are
 1
 2
    overruled. I don't think this is an area where we have to go
   down -- all the way down a rabbit hole, but we'll see what
    this custodial search turns up, and if there's nothing, so be
 5
    it. But it certainly is not the focus of discovery in this
    case. But for the reason that I said, in fairness to the
 7
   plaintiffs, like I said, you're not pulling this out of whole
 8
    cloth. There is a record that -- there is a reason to believe
 9
    issues of this type may have occurred. So that's why the
    objection is overruled.
10
11
             MR. PAREKH: Thank you, your Honor.
12
             MR. FERRETTI: Your Honor, my name is Joe Ferretti on
   behalf the ZHP defendants.
13
             I wanted to just go back for a moment to the
14
    remaining search terms issues, the issues that have been
15
    resolved. Your Honor had mentioned that you would be putting
16
17
    something into the order, and I wanted to ask a little bit
   more about that.
18
19
             THE COURT: You're going to tell me about the Chinese
20
    issue.
             MR. FERRETTI: Yes.
21
22
             THE COURT: Let's talk about that.
23
             MR. FERRETTI: Well, the reason is that the search
24
    terms aren't going to be applied exactly --
25
             THE COURT: I know.
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MR. FERRETTI: -- in the manner that's stated there,
    and I'm afraid that if it's put into an order, then we could
   have complications. We need it to be more flexible so that we
    can work out the translation issues.
             THE COURT: I forgot whose submission it was but
    there was a proposal about I think the defendants go first,
    and they suggest the Chinese translation, and then the
   plaintiffs would look at it, and then you'd meet and confer.
    Is that something you agreed on?
             MR. FERRETTI: Well, I think that we're still
   discussing that.
             THE COURT: Well, we're going to decide it right now.
13
   No more discussion.
             MR. FERRETTI: Well, we do have to consult with
    our --
             THE COURT: Well, you had since August 26 to do that,
    so we're going to decide it right now. You had plenty of time
    to do that. That's why we're here today. Let's decide it.
             What do you want to do? Is it like Japanese where
    different people could look at the same English words and come
    to different versions of how it should be translated?
             MR. PAREKH: There is definitely some of that
    involved. We did have a conversation just before this
    conference, and the suggestion we made, given that they still
25
   have to do some consultation, is instead of having everything
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decided by the January 28th conference, have it decided by
 1
 2
    February --
 3
             THE COURT: What? We're deciding it today.
 4
             MR. PAREKH: No, no, no. I meant the actual
    translations. Because neither -- until we have the search
 5
    terms in English done, we couldn't --
 6
 7
             THE COURT: Isn't that done today?
 8
             MR. PAREKH: That's done.
 9
             THE COURT: All right. Finished.
             MR. PAREKH: So now what defendants are going to do
10
    is go to their translator, and well as the internal company
11
   people, and say, here are the English terms; what are the
12
13
    equivalent Mandarin terms?
             THE COURT: Is that the language, Mandarin, we're
14
15
    talking about?
16
            MR. PAREKH: Yes.
17
             THE COURT: Is that different than Chinese? I don't
18
    know.
19
             MR. PAREKH: It's the normal -- it's what most people
    think of as Chinese. It's the primary dialect.
20
             THE COURT: Okay. So before next Wednesday, there is
21
22
   going to be an agreed-upon list of search terms that's going
23
    to be incorporated into an order, and then in the first
    instance, defendant is going to propose the Mandarin
24
25
   translations, right?
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MR. PAREKH: Correct.
 1
 2
             THE COURT: Give me a date for that.
 3
             MR. FERRETTI: Your Honor, we -- I'm not certain I
    can commit to a date.
 4
             THE COURT: Well, I will give you a date if you don't
 5
 6
    suggest a date.
 7
             MR. FERRETTI: I would say we can go with a date that
 8
   was proposed in -- by plaintiffs of January 3rd, if --
 9
             THE COURT: I'll give you more time than that.
    don't want you working over Christmas.
10
             MR. FERRETTI: I appreciate that, your Honor.
11
12
             THE COURT: How long will it take for plaintiffs to
13
    turn around what you get from defendants?
             MR. PAREKH: At least two weeks, which is when we --
14
    we gave -- this was a little aggressive, I will say, in terms
15
    of our proposal. We had gone -- we had said January 3rd and
16
17
    January 13th. But, given the volume of terms and the
    technical nature --
18
19
             MR. FERRETTI: Your Honor, if I could give a little
20
   bit more context about the complexity. There are many terms
    that have proximities, like within five -- one term within
21
22
    five of another. That doesn't work in simplified Chinese.
    The term -- all of the characters are right next to each
23
24
    other. And so we have to figure out what good -- what strong,
25
    like, alternatives would be to that, to avoid simply putting
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IN RE: VALSRAGAND: 5034 ATUS/DISCOVERY CONFERENCE

an anvil on fire. 1 2 We also have to determine all of the different variants where there are wild cards. Many of the terms have wild cards at the end or at the beginning, and we have to determine all the different variants of what words are actually being sought and then translate each one of those and 7 make each one of those a separate search term. So it seems it 8 would take time for us to negotiate back and forth, and we'll 9 get started on that right away. I think that we could probably have it entirely 10 resolved by the end of January, maybe mid-February. 11 12 THE COURT: So defendants are going to be ordered to 13 propose the Mandarin translations by the 10th of January; plaintiff respond by January 24; and we're going to finalize 14 the order on January 28. 15 16 You have to work this out. There is no way the Court 17 can answer these rulings like you did in Benicar, where you each gave me Japanese --18 19 (Laughter.) THE COURT: You have to work this out. You have to 20 21 work it out. The only alternative is the Court hires a 22 translator and that will be the third person who decides it, and you don't want that. So you have to work this out. 23 24 MR. SLATER: Can I make one request, your Honor? I'm 25 hopeful this can be agreed to. What would be exceedingly

```
helpful to us would be when they propose the search terms to
 1
 2
   us, the Mandarin terms, that they provide to us exemplar
    documents demonstrating those terms in use and context, so
    we're not looking at a naked symbol and just having to decide
   whether it works, but actual documents that they know they're
 5
    going to produce anyway, that actually show the terms in
 7
    context because that will be the most helpful to our
 8
    translators to actually be able to look at that. There is no
   prejudice because the documents would be produced anyway.
    They're getting the terminology from their own documents. I
10
    think that will accelerate our ability to judge and evaluate
11
12
    whether or not those terms are adequate.
             MR. GOLDBERG: Your Honor --
13
14
             THE COURT: I think you have to work this out amongst
    yourselves. I'm reluctant to order them to do that. You have
15
    to collaborate on this. The Court cannot answer this question
16
17
    for you. There is no way the Court can determine which is the
    right Mandarin translation.
18
             MR. FERRETTI: I have confidence we'll be able to
19
20
   work it out, your Honor.
             THE COURT: And if there is a way that -- if they
21
22
    want to see documents and it's not too burdensome, just see if
    you could satisfy their concerns, but you have to work this
23
    out yourselves. Okay? So that will be the direction.
24
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I will put that in the order. Defendants' proposal

25

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by January 10; plaintiff responds by the 24th; no later than
 1
 2
    the 28th, it has to be resolved to put in an order.
 3
             MR. FERRETTI: Thank you, your Honor.
 4
             THE COURT: Unfortunately.
             So we said we would revisit time deadlines after we
 5
    resolved the requests for production, the custodians, and the
 6
 7
    search terms.
 8
             So with regard to the FDA documents, the redactions,
 9
    that's January 31st, with the proviso, Mr. Goldberg, let us
    know if there is a problem and we'll deal with that. That's
10
    the redaction issue.
11
             I guess -- oh, the sales and pricing information.
12
13
    What did we say? 90 days from January 1st? So that would be
    February, March, April 1. April 21 is sales and pricing
14
    documents.
15
             So ZHP can't start their search for documents until
16
    at least January 28th, but the other parties can. So help me
17
    help you, defendants, a date for the production or -- and it
18
19
   will be on a rolling basis.
20
             MR. TRISCHLER: Your Honor, excuse me. I anticipate
    that the production is going to be exhaustive, based on the
21
22
    search terms and the volume of the requests for production of
    documents. In order to compile documents from different
23
   manufacturing facilities, you know, in India, in the United
24
25
    States, and to review those documents and get them in a form
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IN RE: VALSRAGAND: 5037 ATUS/DISCOVERY CONFERENCE

that's ready for production, I submit is going to be a labor-intensive effort. I would like 180 days in order to complete the production. I have no intention of trying to hold up discovery. I'm certainly willing to produce the documents on a rolling basis as we get them and as they become available, and I'm sure the other defendants would agree to that as well. But I'm always concerned about an order with a drop-dead deadline to complete discovery. I want to comply with the Court's order, I want my client to be in compliance with the order, and so 180 days is the period of time that I would suggest.

MR. SLATER: There was two things there.

Your Honor, I think ZHP is not at a complete loss. I mean, there is categories of documents that are not dependent on the search terms. That's the document requests. So that, obviously, can get right into motion. You know, the document requests are not custodial.

And one of the things that we were thinking is, because it's obviously going to be a rolling production, would -- we think it would be very helpful if we could at least prioritize certain categories of documents and certain custodians, based what we know now, to put up at the front of their rolling production -- things like testing results and some of the witnesses, custodians that they have represented would be the most important people, for example. We think

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that would be very helpful to us because at least we can start
 1
 2
    to get what would seem to be most critical earlier on, if that
 3
   would be okay.
             THE COURT: Is that something that the Court should
 4
 5
   get involved in or should I let the parties meet and confer
    about that?
 7
             MR. SLATER: I think we should meet and confer, as
 8
    long as they would be agreeable to doing that.
 9
             And the other thing I would just say, and ZHP,
    obviously, they can run the English search terms through their
10
    documents because all of the documents aren't entirely in
11
    Chinese anyway, but it can start. But if they're open to
12
13
    doing that, to doing the prioritization, then I don't think
    you'll have to get involved unless there is some sort of a
14
    dispute, which I wouldn't anticipate, because, for the most
15
    part, we're going to adopt what they've told us is most
16
17
    important to prioritize because there is no reason not to.
    There may be a few exceptions but --
18
19
             THE COURT: So I will let you talk about that.
20
             Mr. Trischler, if I was going to buy a new car and I
21
    accepted the salesman's first offer, I would feel really
22
   quilty.
             So I'll say, instead of six months, five months, May
23
24
    29th, 2020 -- but, with every order the Court enters, if there
25
    is good cause, good reason, you'll get more time.
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I'll accept that, your Honor, and
 1
             MR. TRISCHLER:
 2
    appreciate the Court providing that amount of time.
 3
             I'm also -- I think Mr. Slater's suggestion about
   prioritizing custodians, if the plaintiffs want to tell us who
 4
 5
    they would like us to start the searches for, we can produce
    those first. That seems eminently fair and reasonable to me.
 7
             And, in the spirit of holiday giving, I'm going to
 8
    ask for one more thing, since we're down to five months. On
    the Court's 483 production order for the -- that was entered
    at the time of the last conference on the macro -- I think it
10
   was at the time of the macro discovery hearing, that the
11
    defendants would have to produce 483s and warning letters with
12
13
    respect to finished dose facilities before it had been limited
    to the API production facilities, I think the order provided
14
    for production by December 31. And I know with respect to my
15
    client, with the holiday season and everything, if we could
16
17
    have an additional -- I'll ask for 30, but if you want to chop
    that down a bit to 20 or something, I'll take it. But
18
19
    December 31, with the holiday, is going to be tough for us.
20
             THE COURT: Let me get that order. Do you have the
21
    order there, what paragraph you're talking about,
22
   Mr. Trischler? That would help me, if we refer to the
23
    specific paragraph.
24
             MR. TRISCHLER: It's Paragraph 6, your Honor, of the
25
   document Number 303, the order of November 25.
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1
             THE COURT: So you want to change the date in
 2
    Paragraph 6 to January 31st from December 31st?
 3
             MR. TRISCHLER: Yes, sir.
             THE COURT: Done.
 4
 5
             MR. TRISCHLER: And I think -- that's all I have,
 6
   your Honor, thank you.
 7
             MR. GOLDBERG: Your Honor, I just wanted to address
 8
    the ZHP timing. If the other defendants are going to start
 9
   whenever they start, and they'll have five months, assuming we
    start February 1 or whatever that -- January 28th, then we'll
10
   have five months from that?
11
12
             THE COURT: Yes.
13
             MR. GOLDBERG: Mr. Slater's suggestion about the
   English search terms being applied, we'll look at that, but we
14
    don't want to do two rounds of searching --
15
16
             THE COURT: And I agree with you.
17
             MR. GOLDBERG: So -- and, likewise, if you want -- if
   plaintiffs' want to prioritize custodians, that would be
18
19
   helpful.
             THE COURT: I think it makes sense.
20
             Okay. So it doesn't appear that we need to -- tell
21
22
   me if I'm wrong. It doesn't appear that we need to get
    together in person on the 18th, does it? Why don't we have a
23
   phone call instead of an in-person meeting. Is 10:00 on the
24
25
    18th okay for everybody for a phone call? By then, we'll get
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VALSRAGAND: 5081 ATUS/DISCOVERY CONFERENCE 121 IN RE:

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the requests for documents, the custodians, the search terms.
 1
 2
             Could you incorporate into a document that we can
 3
    incorporate into an order the protocol that you agreed on with
    the search terms and the hits and all that? And it can
    only -- anyone can be on the call, but it will just be assumed
 5
    just lead counsel, and the only purpose would just be to dot
   the I's and cross the T's.
 8
             Does anyone know -- we moved the January in-person
 9
   meeting to January 28th, right? Is the phone call,
    once-a-month phone call, is that January 15th? Is that the
10
   date?
11
12
             MR. SLATER: I mean, that's the midpoint, but it's
13
    whatever your Honor wants.
             THE COURT: Okay. Let's do January 15th at 4:00.
14
15
    That will be just a phone call.
16
             MR. PAREKH: Your Honor, for the 10 a.m. call, if you
    could possibly make it 11?
17
             THE COURT: Oh, okay. Yes, because you're on the
18
19
    coast?
           11:00 is fine. Yes. Let's make it 11.
20
             MR. PAREKH: Thank you.
21
             THE COURT: So one of the things I was doing is I
22
    like to look six months ahead and where we're going with the
23
    case.
24
             Plaintiffs' fact sheets are going to start to be
25
   rolling in pretty soon, aren't they?
```

```
MR. SLATER: Yes.
 1
 2
             THE COURT: Okay. So, from the defendants'
 3
   perspectives, when you get those fact sheets, is there any
 4
    reason, within say the next six months, you can't take the
 5
   plaintiffs' depositions?
 6
             MR. TRISCHLER: Within six months from the receipt of
 7
   the fact sheets?
 8
             THE COURT: Yes. We're not locking in the date
 9
           I'm just thinking what are we going to be doing the
   next six months? You're going to get these fact sheets, we're
10
    going to be dealing with the defendants' ESI and document
11
   production. We're going to finalize in January the fact
12
13
    sheets for the other defendants within the next couple of
   months. Defendants' fact sheets will be rolling in. And I
14
15
    just want to keep the momentum going in the case.
16
             MR. TRISCHLER: Speaking for myself, your Honor, I
   would think, with the usual caveats, that assuming that the
17
    fact sheets are complete, the medical records have been
18
19
   produced and provided, yes, six months from the receipt of the
    fact sheets should be doable.
20
21
             MS. HILTON: Your Honor, if I may, on the issue of
22
    the plaintiff fact sheets, with respect to the consumer class
    rep, third-party payor fact sheets, and the medical monitoring
23
    class rep fact sheets, we actually would ask for a brief
24
25
   exception, simply because it took some number of weeks to
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negotiate the authorizations that were necessary, to get those
 1
 2
    signed. So I think -- and, similarly, the TPPs are also
    asking for, you know, a brief extension of probably a month
    for those fact sheets. I think right now it's set for January
 5
    3rd.
 6
             THE COURT: Do we have an actual date to answer them
 7
    or was it something like X days after --
 8
             MS. HILTON: It was 90 days after the submission of
 9
    the order, so, in using that timing, I think that landed us on
    January 3rd for the medical monitoring and economic loss fact
10
    sheets. I think TPP may have been --
11
12
             THE COURT: So what would you suggest? February 3rd,
13
    all plaintiffs shall answer fact sheets?
14
             MS. HILTON: That works for the named plaintiffs.
    For the TPPs, I'll let my colleague --
15
16
             MR. MESTRE: The TPP fact sheets were due a couple
17
    weeks after, so if we could get an equivalent time, so maybe
    the middle or end of February would be helpful.
18
19
             THE COURT REPORTER: May I have your name, please?
20
             MR. MESTRE: Jorge Mestre for --
21
             THE COURT: Okay. So February 3rd is what? Whose
22
    fact sheets are going to be produced by February 3rd?
             MS. HILTON: Well, I'm only speaking for the economic
23
24
    loss consumer reps and the medical monitoring representatives.
25
   I don't know if --
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THE COURT: So there's --
 1
 2
             MS. HILTON: -- any personal injury.
 3
             THE COURT: So those are the two class actions,
    right?
 4
 5
             MS. HILTON: Yes, your Honor.
 6
             THE COURT: And the personal injury -- counsel, are
 7
    you talking about the personal injury?
 8
             MR. MESTRE: The third-party payor fact sheets.
 9
             THE COURT: I thought that was the economic loss.
             MS. HILTON: Well, we have three, right? We have the
10
    consumer, the individual consumer plaintiff reps; we have the
11
   medical monitoring individual person fact sheets; and so those
12
13
   were decided and ordered on the same day. Several weeks
    later, the TPP named reps agreed upon a fact sheet, which was
14
    entered into the record, and then triggered the 90-day
15
    timeline. And so there is a staggering between the economic
16
17
    loss plaintiffs, between the consumer and the TPP.
             THE COURT: So the consumer economic loss plaintiffs
18
    class action and the medical monitoring plaintiffs class
19
20
    action, you want till February 3rd?
21
             MS. HILTON: Yes, your Honor.
22
             THE COURT: And the TPP named plaintiffs class
23
    action, you want till March 3rd?
24
             MR. MESTRE: If possible, your Honor.
25
             THE COURT: Done.
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MR. NIGH: Your Honor, for the personal injury, we do
 1
 2
    want a little bit of an extension there. Our due date is
   hitting right at the Christmas time period.
             THE COURT: Yes, there are a lot of those.
 4
 5
             MS. LOCKARD: Well, there is some, your Honor, that
   have already started rolling up. So -- and this is the first
 6
 7
    time we've heard about an extension for the plaintiffs.
 8
             MR. NIGH: Some that are completed already.
 9
             MS. LOCKARD: Right. And we started receiving some,
    fortunately.
10
             MR. NIGH: That's right.
11
12
             MS. LOCKARD: So what is the deadline that counsel
13
   would be asking to move?
             MR. NIGH: Extended to January 15th.
14
15
             MS. LOCKARD: I mean, we don't have an objection if
    it's that period of time.
16
17
             MR. NIGH: For those that would have been due before
    that date, that they would be due by January 15th.
18
19
    there's some that are newly filed cases, and they would
    obviously get 60 days from when they're newly filed.
20
             THE COURT: So all you have to do, when you start to
21
22
    get those fact sheets rolling in, is just look at the record
    from the Benicar case about how we handled the show-cause
23
   procedure. It really worked beautifully, and if we could just
24
25
   do the same thing, that would be great.
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MS. LOCKARD: Sure. Your Honor, I think that's
incorporated in one of the orders, and we've looked at the
Benicar process, so we'll follow or let you know if there
is --
         THE COURT: Yes. So we might actually have an
application for the January 28th conference. I don't know.
There is probably a time to meet and confer. I don't know.
But probably no later than the February phone call.
         MS. LOCKARD: Yes, I think that's right.
         MR. PAREKH: And the parties also have to meet and
confer as to what constitutes a core deficiency versus a
non-core --
         THE COURT: Right.
         MR. PAREKH: -- so we still have that process to go
through.
         THE COURT: Okay. So in the first six months of the
next year, I think it will take us into the next phase of the
case, the actual production phase of the case.
         I do think once we get the named plaintiffs in, just
to keep the momentum going, we can get the named plaintiffs
deposed, and then after -- or substantially -- when the
defendants are substantially complete with their ESI document
production, we'll start taking your depositions. And then, of
course, you'll talk to Judge Kugler about what case he is
going to try and the class action certification issue and the
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Daubert issues, et cetera. Okay?
 1
 2
             MR. PAREKH: Your Honor, just to clarify, when you
 3
    say named plaintiffs, you mean the named plaintiffs in the
    class case, not the individuals?
 4
             THE COURT: Absolutely. Absolutely, yes.
 5
             I think, if I remember right, Judge Kugler's idea was
 6
 7
    to try the economic case first, because that encompasses all
 8
    relevant issues. So I think that, unless he changes his mind,
 9
    that's what he has planned. Okay?
             Okay. I know on this side of the table, you wanted
10
    to talk to Judge Kugler about some Benicar issues, right?
11
    Judge Kugler is in trial. There is going to be a gap between
12
13
    2 and 2:30 when he is available, so if you've got a few
   minutes, if you could go get lunch and come back at 2,
14
    somewhere in that window, we'll talk to Judge Kugler about the
15
    common benefit issues from Benicar. Nothing to do with this
16
17
    case. It's just we're at the tail end of Benicar, and just
    some miscellaneous common benefit issues, and that will wrap
18
19
    everything up.
20
             So you can get a bite to eat and come back at 2,
    sometime between 2 and 2:30, we can meet with Judge Kugler
21
22
    about what he wants to do about those common benefit issues.
             MR. SLATER: So we're not having an afternoon
23
24
    conference in valsartan with Judge Kugler?
25
             THE COURT: I don't see any issues we need to address
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with Judge Kugler about this case. Does anybody see that?
 1
 2
             Okay. So we'll talk on the phone next Wednesday -- I
   purposely scheduled everything to get all of this done before
    Christmas, so we wouldn't have to work over the Christmas
 5
   holiday on search terms and custodians. So we're all grateful
    for that.
 6
 7
             MR. PAREKH: Your Honor, there is just one small
 8
    outstanding issue which is defendants have promised us answers
 9
   to questions -- to the ESI -- for the ESI meeting. We sort of
    stuck that on at the end of the brief. Can we just get a date
10
   by which they have to provide those answers? Because right
11
    now, it's just been sort of we will get them to you.
12
13
             THE COURT: I'm looking at you, Mr. Trischler.
             MR. TRISCHLER: Well, there were only four open
14
    questions that we still owe Behram and his team, so I would
15
16
    say that we could probably get answers to those --
17
             THE COURT: Before Christmas?
             MR. TRISCHLER: Sure.
18
             THE COURT: I think it's to everyone's advantage to
19
20
    get all of this done before Christmas, so you don't have to
    work on this over Christmas -- although I say Christmas.
21
22
   meant the holiday season.
             MR. TRISCHLER: December 23. I don't know where the
23
24
    issues stand with the other defendants, so I don't want to
25
    commit anyone else to that time frame. But as to Mylan, we
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can certainly get those open questions answered in that time
 1
 2
    frame.
 3
             THE COURT: Let's say hopefully get all the answers
    before December 23rd.
 4
 5
             MR. PAREKH: Thank you, your Honor.
 6
             THE COURT: I hope everyone has a great holiday.
 7
    Thank you for your time. And I do sincerely commend you.
    It's obvious that a lot of time and effort has been put into
 9
    this, and I think it's going to be worthwhile in the long
    term. I really do believe that this is the most
10
    labor-intensive part of the case. And once we get over this,
11
    which we will by the end of January, it should be smooth
12
13
    sailing for the rest of the case. Thank you all.
14
             THE DEPUTY CLERK: All rise.
15
             (The proceedings concluded at 1:19 p.m.)
16
17
             I certify that the foregoing is a correct transcript
18
    from the record of proceedings in the above-entitled matter.
19
20
    /S/ Carol Farrell, NJ-CRCR, FCRR, RDR, CRR, RMR, CRC, CRI
21
    Court Reporter/Transcriber
22
    <u>December 17, 2019</u>
23
         Date
24
25
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